

FURTHERING PUBLIC HEALTH SECURITY: PROJECT BIOSHIELD

JOINT HEARING BEFORE THE SUBCOMMITTEE ON HEALTH OF THE COMMITTEE ON ENERGY AND COMMERCE AND THE SUBCOMMITTEE ON EMERGENCY PREPAREDNESS AND RESPONSE OF THE SELECT COMMITTEE ON HOMELAND SECURITY HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

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THURSDAY, MARCH 27, 2003

HOUSE OF REPRESENTATIVES, COMMITTEE ON ENERGY
AND COMMERCE, SUBCOMMITTEE ON HEALTH, JOINT
WITH THE SELECT COMMITTEE ON HOMELAND SECU-
RITY, SUBCOMMITTEE ON EMERGENCY PREPAREDNESS
AND RESPONSE

Washington, DC.

The subcommittee met, pursuant to notice, at 9:30 a.m., in room 2123, Rayburn House Office Building, Hon. Michael Bilirakis (chairman) presiding.

Members present from the Subcommittee on Health: Representatives Bilirakis, Greenwood, Burr, Norwood, Wilson, Ferguson, Rogers, Tauzin (ex officio), Brown, Waxman, Eshoo, Stupak, Green, Capps, and Dingell (ex officio).

Members present from the Subcommittee on Emergency Preparedness and Response: Representatives Shadegg, Weldon, Tauzin, Shays, Camp, Diaz-Balart, King, Souder, Thornberry, Gibbons, Granger, Sessions, Cox, Thompson, Harman, Cardin, DeFazio, Lowey, Norton, Pascrell, Christensen, Etheridge, Lucas and Turner.

Also Present: Representative Dunn.

Staff present: Brent Del Monte, majority counsel; Steve Tilton, health policy coordinator; Eugenia Edwards, legislative clerk; John Ford, minority counsel; and Jessica McNiece, minority staff assistant.

Mr. BILIRAKIS. Would everybody please take their seats. Good morning. I do wish to announce to the members that Secretary Thompson, who is the first panel, has to leave by 11:30 to 11:45 at the latest. So I would very much appreciate, on behalf of myself, Mr. Brown, Mr. Shadegg and his ranking member, if we could waive as many of our opening statements as possible so we can get to the Secretary.

I now call this joint hearing of the Energy and Commerce Health Subcommittee and Select Committee on Homeland Security Emergency Preparedness and Response Subcommittee—what a moniker—to order.

I would like to thank all of our witnesses for appearing before both of our subcommittees today and, in particular, I would like to recognize Secretary Thompson and thank him for taking the time to be with us for the second time during this 108th Congress.

Last year, the Energy and Commerce Committee worked together in a bipartisan fashion to produce the Public Health Secu-

rity and Bioterrorism Response Act which President Bush signed into law in June of last year. I was proud to have been a part of this important effort. However, while our legislation has helped get critical resources out to the States and moved us closer to the reality of a comprehensive strategic national stockpile, more certainly needs to be done, and that is largely why we are here today.

The possibility that our enemies might attack us with biological weapons remains a very significant threat. Unfortunately, while there has been tremendous and rapid progress in the treatment of many serious naturally occurring diseases, the medical treatments available for some types of bioterrorist attacks have improved little in decades.

President Bush has proposed a strategy to deal with this obvious weakness in our defenses, and that strategy is encompassed in the administration's Project Bioshield proposal which we are here to discuss further today.

I will let Secretary Thompson describe the details of this new initiative during his testimony. I do want to commend the President for offering this thoughtful proposal, and to anticipate that, if implemented, it will harness the power of our research driven pharmaceutical, biotechnology and medical technology industries in developing effective biomedical countermeasures.

I am also interested in hearing about some of the challenges affected stakeholders will face in Project Bioshield, if Project Bioshield becomes a reality. We have a great deal of expertise in our second panel, and I hope the members take advantage of this opportunity.

We are all here today, of course, with a very heavy heart. As our Nation commits to securing our safety overseas, it remains our responsibility to do what we can to ensure that the United States is ready for whatever bioterrorist threat we might face.

Having said that, I say thank you, and I now yield to my friend, the gentleman from Ohio, for an opening statement.

Mr. BROWN. Thank you, Mr. Chairman. Welcome, Secretary Thompson. Welcome, Dr. Fauci.

Expanding our arsenal of vaccines, antibiotics and other bioterrorism countermeasures is a shared goal, and I appreciate the administration's proactive efforts in that way. While I have questions about the funding mechanism and would like to understand more about the drug development contracts envisioned, I am confident we will work on a bipartisan basis to move this initiative forward.

In that context, I hope the administration will consider additions that would materially increase our chances of achieving that objective. In addition to expanding and diversifying our supply of countermeasures, we must protect the weapons already in our arsenal. That means addressing anti-microbial resistance.

When bacteria are exposed to antibiotics, resistant strains survive and proliferate, posing other new threats to human health. This phenomenon makes it more difficult and vastly more expensive to treat a host of infectious killers and, unlike other medical challenges, there is no way to eradicate antimicrobial resistance. But by properly managing antibiotics, we can render resistance less dangerous, less costly.

If we don't take appropriate steps now to encourage the development of new antimicrobial therapies and cut back on non-therapeutic antibiotic use, defending against bioterrorism will be far more difficult in the future. It makes sense to incorporate strategies to combat antibiotic resistance into Project Bioshield.

Second, access to bioterrorist countermeasures is a function of availability and a function of price. In 2001, faced with weaponized anthrax, the administration was forced to haggle with Cipro makers for a price we could afford. Faced with building a stockpile of medicines to protect Americans from biological warfare, Mr. Secretary, you put it plainly, saying the price is the question.

If prices are too high, we will be unable to buildup sufficient stockpiles. Public officials may be forced to cut corners. In the ensuing dispute the administration acknowledged that the Federal Government did, in fact, have the right to secure generic versions of Cipro, but was also concerned about the uncertain royalty payments that would be required.

I introduced legislation last year aimed at addressing the constraints the Federal Government faced in securing Cipro. Under that bill, patent holders would be entitled to reasonable compensation, which they deserve as the product innovator, but the Secretary would have the authority to determine the reasonable compensation for use of a patent in a public health emergency under criteria which strike a balance between the need to maintain incentives for new drug development and the need to protect the public health.

Project Bioshield certainly aims to spur R&D, as it should. Some would argue the safeguards I have proposed will mute this incentive. To that, I would answer that virtually every developed nation other than the U.S. has compulsory licensing laws on the books that apply to prescription drugs.

Drug companies develop and market drugs, obviously, in all of these countries.

In an ideal world, we could ignore the price component of the access equation, because it is invariably the most difficult to deal with. R&D is a tradeoff. If prescriptions are too expensive to reach those who need them, their inherent value is diminished, and the value of the R&D that went into them is also diminished. Price is important.

Secretary Thompson, my compulsory licensing bill is one way to address pricing concerns, but it is not the only way. I would appreciate the opportunity to discuss price considerations with you as we move forward with Project Bioshield.

I want to raise one more issue. If there is one lesson we have learned since September 11, it is that public health threats change and evolve. That principle obviously applies in developing as well as developed nations. Over the last several months, attempts have been made to modify the so called DOHA Declaration which promotes the ability of developing nations to secure lower price medicines to combat public health crises.

The modifications would limit—that our government sought would limit the definition of public health threats to a handful of infectious diseases. Needless to say, bioterrorist attack was not included in that definition. This static and stringent definition ig-

nores the reality that public health threats are diverse, and they change over time.

This definition effectively locks developing nations into a cycle of poverty and disease and death. As we fight to protect the health and lives of Americans, I urge you, Mr. Secretary, to also fight for the health and the lives of individuals in impoverished.

Your chairmanship of the global fund is a major, major commitment and step, and we are also pleased with that. I urge you to put the weight of the U.S. behind preserving the original intent of the DOHA agreement.

I thank the chairman.

Mr. BILIRAKIS. The Chair thanks the gentleman and now yields to the co-chairman of this hearing here today, a very valued member of the Energy and Commerce Committee and my health committee as well as the chairman of the Subcommittee on Emergency Preparedness and Response of the Select Committee on Homeland Security, Mr. Shadegg.

Mr. SHADEGG. Welcome, Secretary Thompson, and thank you very much, Chairman Bilirakis, for this synergistic effort between the Energy and Commerce Subcommittee on Health and the new Select Committee on Homeland Security's Subcommittee on Emergency Preparedness and Response.

It is a distinct pleasure for me to co-chair this first ever hearing of a subcommittee of the Select Committee on Homeland Security, and first ever hearing, of course, of the Emergency Preparedness and Response Subcommittee.

Now last November the Congress took a monumental step in re-ordering the priorities of the executive branch to put the Federal Government in a position to better protect American citizens and secure our borders by passing the Homeland Security Act.

Among the functions that have been transferred to the Department of Homeland Security dealing with emergency preparedness and response include: the Federal Emergency Management Agency; the Integrated Hazard Information Systems, formerly at the National Oceanic and Atmospheric Administration; the National Domestic Preparedness Office of the FBI; and the Domestic Emergency Support Teams of the Department of Justice.

There are two critical missions that have also been transferred to DHS which are particularly pertinent to today's hearing, those of the Office of Emergency Preparedness in the National Disaster Medical System, and the Metropolitan Medical Response System, as well as the strategic national stockpile.

It goes without saying that September 11, 2001, was a wake-up call for our country. I think we all knew about the potential threat for terrorist acts to take place in our homeland, but for a lot of us those were big concepts outlined by think tanks and policy experts.

Only a month later we were faced with the prospect of anthrax mailings to New York, Washington, and your state, Mr. Chairman, Florida. That is when we discovered that the delivery mechanism for terror can take on a completely different look than a crude bomb or a lone gunman.

We took our first step in addressing the new bioterrorism threat by passing the Bioterrorism Preparedness and Response Act overwhelmingly last year. Among the law's provisions was \$1.15 billion

in new funding to expand the country's national stockpiles of anti-bioterror drugs and vaccines, and for the purchase of additional smallpox vaccines.

Today, we embark on a further effort in that war on terror, Project Bioshield. In an effort to energize and unleash the ingenuity of our Nation's best biomedical minds, Project Bioshield will direct the national Institutes of Health to accelerate research and development in the area of biochemical countermeasures. It will allow the Secretary of Health and Human Services the ability to procure biomedical countermeasures, and last it will give the Secretary the authority and ability to accelerate the introduction of unapproved drugs, devices, and biologicals to help the threat to American lives in an emergency.

I look forward to the opportunity to fully explore all of the issues surrounding this creative proposal from the administration to address the bioterrorism threat that our Nation faces, including the question of mandatory or discretionary funding, whether there should be a sunset date so that Congress can take stock of the success or failure of this program, whether this effort will be enough to stimulate the interest in the private sector to produce the drugs and devices needed to protect American lives, and how much of the money devoted to this research will go—devoted to this task will go into research versus acquisition and countermeasures.

Chairman Bilirakis, I welcome the Secretary here and look forward to the testimony of all of our witnesses, and yield back.

Mr. BILIRAKIS. I thank the gentleman, and on behalf of Mr. Shadegg the Chair now yields to the ranking member of his subcommittee, Mr. Thompson.

Mr. THOMPSON OF MISSISSIPPI. Thank you, Mr. Chairman. In my capacity as the new ranking member of the Select Homeland Security Subcommittee on Emergency Preparedness and Response, it is with great pride that I have the opportunity to sit before you today to address and voice my concerns on an issue that is paramount in the minds of all Americans, safeguarding the United States against all acts of terror.

In the wake of September 11, it has become apparent that America, unfortunately, is vulnerable to a vast array of terrorist attacks, not only attacks carried out through conventional means but unconventional, biological, chemical or radiological means as well. Being cognizant of all the possible threats lurking out there, we in the Federal Government must do everything within our means to give Americans peace of mind by knowing that this country has adequate countermeasures.

It is quite evident that the country currently lacks the necessary medical countermeasures to deal with the acts of bioterrorism. In a recent study, the Defense Science Board found that the country has only 1 of 57 countermeasures required to deal with the top 19 bioterror threats. This means we need to be more than just a second generation smallpox and anthrax vaccine to guarantee the Nation's safety.

In order to completely guarantee safety, we need a host of not just new vaccines but new diagnostic and therapeutics as well. I hate to imagine the pathogens out there that we have yet to encounter.

In the past couple of weeks along, we have witnessed the emergence of a new virus, acute respiratory syndrome, SARS, for which we do not have treatment for spreading throughout Asia. Then thinking long term, we have to address the possibility of hybrid threats or genetically modified threats made to resist antibiotics.

I say all this not to be an alarmist, but it is just to underscore the importance of the task at hand. I am pleased that the administration, acknowledging the grave potential for unconventional attacks, has created a dialog within Congress in hopes of resolving our Nation's deficient preparedness by unveiling Project Bioshield.

Within a goal of stimulating new and accelerating existing biomedical research, bolstering the Nation's countermeasures stockpile, and implementing mechanisms to make such countermeasures widely available in the event of an emergency, Project Bioshield is an ambitious and very necessary proposal, long overdue. However, I do have some concerns regarding the legislation in its current form.

I am concerned that the legislation is much more focused on the short term procurement of countermeasures than long term research. Also, I am concerned at the way the legislation treats companies potentially involved in or considering doing research in developing biological countermeasures.

The legislation seems to offer narrow incentives for companies to get involved. It doesn't seem to promote competition among companies, and I am concerned that the legislation doesn't seem to provide an adequate recourse for companies to appeal decisions made by the Secretary.

Mr. Chairman, this concludes my opening statement. Mr. Secretary, it is good to have you with us here today. I look forward to hearing your testimony, as well as the rest of the distinguished panel.

Mr. BILIRAKIS. The Chair thanks the gentleman, and now yields to the chairman of the full Energy and Commerce Committee, Mr. Tauzin.

Chairman TAUZIN. Thank you, Chairman Bilirakis. I have two welcomes, first of all, first to Chairman Shadegg and to the members of the Select Committee on Homeland Security.

Chairman Shadegg is no stranger to this committee room. He is a distinguished member of the Energy and Commerce Committee, but I want to welcome all the members of the Homeland Security Select Committee as this, I understand, is the first of the joint subcommittee process by which we will continue to do our work in conjunction with the work that Chairman Cox will do on the important select committee that has been created for this extraordinary and emergency problem our country faces at this time.

I want to welcome all of you Democrats and Republicans to this distinguished room where so much work on protecting our country goes forward. I particularly want to thank again Secretary Tommy Thompson for coming personally to make the administration case on the Bioshield initiative, and thank you, Secretary Thompson, for several things. One, of all the people whom our committee has jurisdiction over in terms of their agency work, you have been the most forthcoming, the most cooperative and helpful in helping us develop policy for our country of anyone that I am aware of, and

I want to thank you and your staff for that extraordinary level of cooperation, your personal commitment to work with our committee as we go forward.

Second, great thanks for the work done in the last Congress on the bioterrorism bill which this committee produced. I believe that is going to pay great dividends in helping to secure our country.

What you bring to us today makes all the common sense in the world. You basically make a case, as we should all make a case, where the market cannot do something critically important for our country, that we've got to step in and make sure it happens. In this case, there is no market for a plague vaccine, for example. No one in their right mind is going to spend scarce resources to develop a vaccine for a plague when there is no plague yet and there is no market for that vaccine.

If we don't in government create a market, create an incentive for companies to develop the vaccines that are critical to protect us against diseases we thought had been wiped out and eradicated, but all of a sudden might pose a threat to our country in a terrorism sort of venue, who will produce that vaccine for us if we don't have a special program to make sure it gets produced and that Americans are protected because someone took the initiative to make sure that that was available for the tens of millions of Americans who might need it.

Likewise, while no one wants to at all threaten the gold standard of Food and Drug Administration approval of drugs, if we were to have a bioterrorism attack against this country and we would be faced with the need to vaccinate and to treat millions of Americans, and there was a vaccine or a drug waiting approval that had all the evidence of being able to protect this country, why would we want to let the process stand in the way of dealing with that kind of an emergency.

So you bring to us this initiative that basically gives our country in this extraordinary time, one, the ability to make sure there is in fact an incentive to produce the things critical to protect our country when the market might not otherwise do it, second, to make sure that we stand aside the normal processes, should the worst ever happen and we face that dramatic emergency, and we are prepared at that point to use whatever resources that might be available in the process, whether yet approved or not, to protect our citizens from that kind of harm.

That is the kind of thinking we have asked all the agencies to do and the kind of initiatives we have asked them all to bring to us. We don't think like evil people in America. We are generally good people. When a plane went down when some pilot decided to commit suicide out of New York, most of us were thinking, you know, if he wanted to die, why didn't he just kill himself. Why did he have to take all the passengers down with him.

In a cave in Afghanistan, Osama bin Laden was thinking, you know, if you just crash that plane into a building, we could kill more Americans. Evil people think differently than we do, and we've got to force ourselves to take these kind of initiatives and to think through the worst case scenarios that might happen to our country. I want to thank you for doing that.

I want to thank you and the incredible staff you have for thinking of our country in that extraordinarily sensitive and, I think, productive way and for helping this committee do the right thing.

Again, Mr. Chairman, thank you and, Chairman Shadegg, thank you, and if you will extend my thanks to Chairman Cox for the extraordinary way in which these two committees, I think, are going to work today and continue to work in the future. I yield back.

[The prepared statement of Hon. W.J. "Billy" Tauzin follows:]

PREPARED STATEMENT OF HON. W.J. "BILLY" TAUZIN, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

Mr. Chairman: I commend you for calling this hearing to examine the Administration's Project BioShield proposal. Further, I would like to extend a special welcome to the Members of the Homeland Security Subcommittee on Emergency Preparedness and Response, who have joined us today. Also, while I look forward to hearing from all of our witnesses here today, I am especially grateful that Secretary Tommy Thompson has taken the time out of his busy schedule to join us to explain Project BioShield.

There is no doubt that in these troubled times we should become increasingly vigilant against the threat of bioterrorism. While we are doing so much more now, on a proactive basis, to protect the American people from those wishing to do harm, we must still prepare for the worst.

Project BioShield is a proposal which will help us prepare for the contingency of bioterrorist attack. Not only would it provide the government with better flexibility in terms of countermeasure research and development, but it also will create a market so that private companies will develop countermeasures for use in the event of an attack.

Presently, it makes little sense for a drug or vaccine manufacturer to commit their scarce resources toward developing a countermeasure for, say, the plague. There is just no market for a plague vaccine. Project BioShield, however, would have the government create the market through ample funding. While I have concerns about the mandatory spending component of this proposal, I want to work with the Administration to ensure that whatever market we create is adequately funded in order to spur private development of countermeasures.

Finally, the proposal would allow the use of unapproved drugs, vaccines, or devices in times of emergency. This proposal makes perfect sense. If there is a clearly superior vaccine on the cusp of FDA approval, yet for whatever reason approval has not been finalized, then it should be made available in times of emergency. This especially makes sense if we need to have tens of millions of people vaccinated in a matter of days. No one wants to replace the current "gold standard" at FDA through this proposal—rather, we need to provide the Secretary with utmost flexibility in times of health emergency.

Again, I commend you for holding this hearing today. I look forward to the testimony of the witnesses.

Mr. BILIRAKIS. Thank you, Mr. Chairman. The Chair now yields to the ranking member of the Select Committee, Mr. Turner.

Mr. TURNER. Thank you, Mr. Chairman. It is an honor to be able to join with you today in this joint hearing of the Health Subcommittee of the Commerce Committee and our Emergency Preparedness Subcommittee of the new Select Committee on Homeland Security.

I had the opportunity to have a briefing from Secretary Thompson and Secretary Ridge a few weeks ago at the White House on this proposal. I think I join with all of us in the commitment to take care of this task with dispatch. The truth of the matter is there is no greater threat to our security than that represented by bioterrorism. Short of nuclear attack, there is no threat that can have the catastrophic loss of life that could result from bioterrorism.

So this is a matter that clearly should be a priority of this Congress, and I am confident that we will be able to move this legislation with dispatch to ensure that we get on with the task of preparing to address these threats.

I would like to say, and I hope Secretary Thompson will address this, that I have heard some concern since the initial briefing that we received about the unlimited power of the purse that is contained in the initial draft of the legislation, and Congress obviously will want to maintain its traditional role and constitutional responsibility regarding the funding of this project.

I think there are some areas of the bill that could be strengthened to provide greater reporting and oversight by the Congress. Having said that, I do believe very strongly that these differences need to be settled rapidly, because this legislation needs to move forward as quickly as it possibly can.

With that, Mr. Chairman, thank you again for the opportunity to join with you in this hearing.

Mr. BILIRAKIS. Thank you, Mr. Turner, and I see that Mr. Dingell, the ranking member of the Energy and Commerce Committee, has just arrived. Opening statement, Mr. Dingell?

Mr. DINGELL. Mr. Chairman, thank you for your courtesy. Mr. Secretary, Doctor, welcome this morning. Thank you for holding the hearing, Mr. Chairman. As we continue to focus our attention on the very important and time sensitive issue of preparing for the possibility of a biological, chemical or radiological attack, I look forward to hearing from our witnesses, and I am particularly pleased to welcome our good friend from the University of Michigan, Dr. James Baker.

We are here today to examine the administration's proposed Bio-shield Act of 2003. It has three components. It seeks to accelerated research at NIH for the purposes of developing biomedical countermeasures. It proposes a guaranteed market to manufacturers of drug and medical device countermeasures, and it authorizes new Food and Drug Administration emergency use authorization for products and treatments still under development.

The overall goal of the legislation has merit. Some of the specific provisions are cause of concern, and I think you could have heard my concern in the statement which I just made, pointing particularly to the emergency use authorization for products and treatments still under development.

I would say that I am anxious to learn about them, and I want to hear what will be done to protect the American public. I am also curious, however, what will happen with regard to the unlimited, unfettered future appropriations without limits and without constraints. This is a blank check of the most extraordinary character that I have ever seen, and I will look forward to see how this is going to work, particularly with regard to its impact on basic procurements laws which are aimed at preventing waste, fraud and abuse.

I could observe that this is very possibly a very bad idea and will need to be inquired into carefully by the committee. There are other questions of interest, I think, with regard to Project Bioshield Act of 2003. How will the government price products under the 5-year contract specified in the bill? Why does the bill allow for dis-

count prices for unlicensed and unapproved products? Shouldn't there be more specific definitions for certain terms contained in this bill, such as product, significant market, and pressing research needs?

Mr. Chairman, I thank you for recognizing me, and I thank our witnesses for their help as we begin forging the useful and well intended administration proposal into what I hope will be more sensible and workable legislation.

Mr. BILIRAKIS. The Chair thanks the gentleman. As I announced early on when not too very many members were here, Secretary Thompson has limited time. He can only be here until approximately 11:30, maybe 11:45 at the latest. I would ask the members, if they possibly can, to waive their opening statements and to take that 3 minutes during their question time so they might have 8 minutes after that, but obviously I can't shut off, and will not shut off, any opening statements.

So having said that and hoping to receive your cooperation, the Chair now yields to Mr. Shays.

Mr. SHAYS. I will waive my opening statement.

Mr. BILIRAKIS. All right, sir. Ms. Harman.

Ms. HARMAN. Thank you, Mr. Chairman. I am happy to be back on this committee. I miss my service here, and I will look forward to returning to it very soon.

I also want to welcome our guests, particularly Secretary Thompson, and thank you for enormous effort on behalf of the public health system of America. I want to thank you specifically on behalf of the residents of L.A. County who are going to keep our trauma system open because of the efforts by you, Tom Scully and others in your department. Thank you very much. It is a very, very big deal to southern California.

I just wanted to say a few things about this legislation and try to put it in a context. As you know, I am the ranking member on the House Intelligence Committee, a high honor, I must say, and I am absolutely persuaded that the United States faces a real bioterrorism threat now.

That makes it absolutely critical that we address market failures, as this bill intends to do—this program intends to do, to make certain that we have the antidotes and toxins and other medical agents that can help us respond effectively. I don't think this legislation is perfect.

There are deficiencies that have been addressed by others. I think we should work together to address those deficiencies in structure and funding quickly and pass this legislation. A good model is the Bioterrorism Act that we passed last year. I was proud to play a small role in that. We worked together, and we were able to pass, I think, the first really important piece of homeland security legislation on a basically unanimous basis through the House of Representatives. That is a very good thing.

Let me just tick off a few other issues that are out there that require urgent attention. One of them is not addressed by these committees, but it is proliferation of biological and chemical weapons. We have to get a hold on that. If we don't, we are going to continue to have this problem.

Another is better information for the public about what to do in the event of a biological or chemical attack. That part of our warning system still needs work.

The third, I would say, is a good program which we should agree on within the next week to make certain that our first responders want to get vaccinated with the smallpox vaccine so that they can protect the rest of us.

Lois Capps on this committee has some extremely good ideas. I would urge the administration to reach for those ideas, incorporated in the administration program, so that we can get a truly bipartisan and effective piece of legislation on the floor.

Thank you, Mr. Chairman.

Mr. BILIRAKIS. Ms. Granger? Mr. King? Mr. Weldon? Thank you. Dr. Christensen.

Ms. CHRISTENSEN. I will reserve my time, Mr. Chairman.

Mr. BILIRAKIS. Thank you, Doctor. Ms. Lowey. Thank you. Mr. Burr. You waive it? Good. Mr. Stupak.

Mr. STUPAK. I waive my time, Mr. Chairman.

Mr. BILIRAKIS. Thank you. Mr. Diaz-Balart.

Mr. DIAZ-BALART. Thank you, Mr. Chairman. Mr. Secretary, since I also have conflicting responsibilities—I am sure many of us do—and I would like to hear your testimony, I waive my opening statement.

Mr. BILIRAKIS. The Chair thanks the gentleman. We are moving right along here. Mr. Etheridge.

Mr. ETHERIDGE. Thank you, Mr. Chairman. I will waive my time until we get a chance for questions. Thank you.

Mr. BILIRAKIS. Thank you. Mr. Norwood, Dr. Norwood.

Mr. NORWOOD. Thank you, Mr. Chairman. Out of respect for the Secretary, I will waive my time and will require the 8 minutes.

Mr. BILIRAKIS. Thank you. I am sure you will. Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman. I will put my statement in the record and save my time for the 8 minutes.

Mr. BILIRAKIS. Thank you. Of course, the written statement of all members of both subcommittees is made a part of the record, obviously, with unanimous consent. Mr. Souder. Thank you. Mr. Lucas.

Mr. LUCAS. I waive my time.

Mr. BILIRAKIS. Ms. Dunn.

Ms. DUNN. Thank you, Mr. Chairman. I will waive my time, and only say to the Secretary, thank you for being here and bringing to public knowledge the insights you have into Project BioShield. I think it is vitally important that folks at home know how much preparation is being done to provide for their security.

Mr. BILIRAKIS. Mr. Pascrell.

Mr. PASCRELL. Mr. Chairman, I will submit a longer statement, but I want to, first of all, greet the Secretary and ask the Secretary to address the issue of oversight. While we are trying to expedite here, while we are trying to discover agents that need research in working with the pharmaceutical industry in this country, this Congress cannot relinquish its right to have oversight. We do that with an Apache helicopter. We must do it with anything that we are going to do to respond to bioterrorism, and I ask the Secretary to address that issue of Congressional oversight during the process.

Thank you, Mr. Chairman.

Mr. BILIRAKIS. Thank you. Mr. Kemp. Mr. Rogers. These are people who were here, but who have stepped out. Mr. Waxman. Ms. Eshoo.

Ms. ESHOO. Thank you, Mr. Chairman. Good morning to you. I will place my opening statement in the record and reserve my time. Thank you.

Mr. BILIRAKIS. I thank the gentle lady. Mr. Sessions.

Mr. SESSIONS. Mr. Chairman, I seek no time. Thank you.

Mr. BILIRAKIS. Ms. Capps. Thank you.

Well, does that cover everybody? All right, the Chair really appreciates your cooperation.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. BARBARA CUBIN, A REPRESENTATIVE IN CONGRESS
FROM THE STATE OF WYOMING

Thank you, Mr. Chairman.

We must be deliberate as well as responsible in how we go about developing any plan to combat biological and chemical agents.

The possibility of such an attack in the United States is unnerving to all of us. We know the threat to be real so we must do whatever necessary to protect the citizens of this country—and we are.

The Administration has presented us with Project Bioshield, and we are here to see if it meets the expectations of today. From what I know of it, I am encouraged.

It is designed to spur innovation in the manufacturing and development of biological countermeasures.

It gives NIH the flexibility to concentrate more research in this area. It provides mechanisms to get new drugs and technologies to the public faster when no alternatives exist.

These are the kinds of things we must have in place if we are to be truly prepared for this type of warfare. I commend Secretary Thompson, his department, and the Administration in their efforts to do just that.

I do however have questions today about the proposal. More specifically as they relate to liability protections, what it means to deal with highly dangerous pathogens, and the viability of producing drugs and devices solely for bioterrorism prevention.

I'm simply interested in developing the best biological defense plan that we can. That will most assuredly require the collaborative efforts of everyone at the table today, and then some.

We are in unchartered territory these days so we must be careful and thorough in how we go about this. It is also obvious however that time is not on our side.

With that, Mr. Chairman, I look forward to hearing from our witnesses today, and yield back the remainder of my time. I63

PREPARED STATEMENT OF HON. DONNA M. CHRISTENSEN, A DELEGATE IN CONGRESS
FROM THE VIRGIN ISLANDS

I want to welcome Secretary Thompson, the first official witness that we the members of the newly constituted House Select Committee on Homeland Security will get to hear from.

Today we are here to examine the Project Bioshield Act of 2003, the purpose of which is to increase the development of countermeasures to bioterrorism, and facilitate their approval for use and mass production, so that they would be readily available when needed.

While research and development of such products is important, I think our time would have been better spent on “furthering the question of Public Health Security”—a broader and more immediate issue.

At this first meeting of the Subcommittee on Emergency Preparedness and Response, which I am honored to serve on, I want to say that that is my primary concern.

We have long had deficiencies in our public health system. With the impact of rising health care costs due to our lack of focus on prevention and ensuring everyone's equal access to quality health care, and the systems continued deterioration, because of cuts in funding and misdirected policies, the nation's public health infrastructure is in a worse position to provide health security today than ever before.

Even if we had the vaccines, medications and devices today to counteract all known or predictable bioterrorism agents, we would be stymied by the inability of public health systems in many parts of our country to act efficiently and effectively.

So I hope we will spend an appropriate amount of time on the issue of public health security, particular because it takes upwards of 5, maybe as much as 15 years to develop new vaccines or therapies.

We can't wait that long for protection.

On the particular bill before us today, I have concerns about the broad powers of the Secretary of HHS; the open ended funding; the expedited procedures to make the countermeasures available for use, and what might be a lack of important safeguards.

In conclusion let me once again welcome Secretary Thompson to this joint Subcommittee hearing today. I look forward to receiving your testimony, and the testimony of all of the witnesses before us today. I also look forward to working with you and your Department in developing a meaningful solution the Public Health Security needs of country as we continue to face the growing threat of terrorism and in our country. Thank you.

PREPARED STATEMENT OF HON. BOB ETHERIDGE, A REPRESENTATIVE IN CONGRESS
FROM THE STATE OF NORTH CAROLINA

Thank you to both of our Chairmen for holding this hearing. This proposal is an extremely important element in our nation's war on terrorism, and I appreciate the opportunity to hear Secretary Thompson describe the legislation.

I have a number of research institutions and pharmaceutical development companies in my district, and many of them have expressed an interest and desire to help defend our country from terrorist threats. Project Bioshield is an interesting proposal and a good place to begin the discussion of our support of scientific research and development.

However, the measure also raises a number of questions and concerns regarding the lack of funding oversight by Congress, the potential safety of products rushed through an expedited approval process, and the extreme liability limits that would prevent those harmed or killed from the use of the countermeasures from receiving reasonable compensation.

The best defense against terrorism is to *prevent* attacks. However, I know that a determined enemy can breach even the best defenses our country can provide, so we must also be prepared to respond to all threats. Thank you again for giving us the opportunity to begin discussions about this important proposal.

Mr. BILIRAKIS. Having said that, I would now recognize Chairman Thompson. We will set the clock at 10 minutes, sir. Obviously, to get your message across, you will take whatever time you please. Please proceed.

STATEMENT OF HON. TOMMY G. THOMPSON, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES; ACCOMPANIED BY ANTHONY FAUCI, NATIONAL INSTITUTES OF HEALTH

Secretary THOMPSON. Good morning, Mr. Chairman. I would just like to thank each and every one of you for giving me this opportunity to appear in front of this august body and to be able to talk about a very important subject. I thank all those individuals who have waived their opening remarks and, hopefully, have enough time to answer each and every one of your questions.

The truth of the matter is, Mr. Chairman, we have a serious problem in America. When I took over as Secretary of the Department of Health and Human Services a little over 2 years ago, I found that we were ill prepared to deal with a bioterrorism threat. Subsequent to that time, we have done a lot of things.

We purchased enough smallpox for every man, woman and child in America. We have put in place many different innovative ways to do research. We are looking for more. We also have developed

probably one of the most modern communication—technologically advanced communication rooms dealing with information, dealing with tracking information on diseases and storms anyplace in the world.

I would advise and suggest and invite each and every one of you to come over to the department and see it. I think, if you walk through it, you would see how well prepared we are to respond to any kind of chemical, biological or radiological event that may take place in our country, and I would invite each and every one of you, and hope you would do it when I can take you personally through it.

Second, there are six counter-agents, bioterrorist agents that we are very concerned about. The first one, of course, is smallpox. The second one is anthrax. The third one is botulinum toxin. The fourth one, of course, is plague. The fifth one is the hemorrhagic fever viruses which includes ebola, and the sixth one is tularemia.

We are also concerned about modifying any one of these bioterrorist agents, and we do not have the capacity, ladies and gentlemen, to really respond quickly. That is why my department, under the auspices of people in my secretarial office and also with the good support and ingenuity of people like Dr. Fauci at NIH, we have come up with Bioshield which I will explain to you in a moment.

Before I begin, I thought it would be helpful to give you a brief update on SARS. As we speak, scientists from a number of countries are working around the clock to solve the mystery of SARS. In fact, this morning before I came over here, we had a teleconference with the WHO.

There are approximately 1500 cases now, and it is spreading a little bit faster than we had anticipated. There are 45 cases in the United States, and we do not know—have not been confirmed that are SARS, but are cases that we are investigating.

Now we are also working around the clock to solve the mystery of SARS. Most of the laboratories around the world had determined at the first blush that this was a paramyxovirus which is in the family of the viruses of measles and mumps and pneumonia. Our scientists question that, and luckily so. Our scientists at CDC came up and decided that this was the coronavirus or the common cold, but it is a generation removed from the cold and is much more virulent, and approximately 4 percent of the people that get SARS currently have died.

So we are very, very concerned about it. We do not know how to control it as of yet. We do not have a therapy for it yet, but we are working around the clock to develop it, and I Thought you individuals would want to know that.

Mr. Chairman, my goal at HHS is to do everything I possibly can to ensure that Americans are strong, that they are health and independent. Every time we take a dollar from the taxpayers, we must be confident that we can use that dollar in order to promote their health, security and independence better than they can, and that is our solemn responsibility and one that I take very seriously.

Private investment should drive the development of most medical products. Bioterrorism, however, is different. None of us ever expected that 16th century illnesses and diseases could be used and

be weaponized and can be used as bioterrorist threats in the year 2003, and that is what we are facing.

There is no market out there to develop the vaccines, the antiviruses, the antidotes and the antibiotics. That is why Bio-shield was developed, and we worked very hard to come up with a procedure in which we could accelerate the research, accelerate the purchase and accelerate, if need be, the emergency usage of that particular medicine or vaccine or drug.

The attacks of September 11 made it clear that the threat of terror is graver and more imminent than at anytime in modern history. The anthrax attacks made it clear that the threat of terrorism includes weapons of unprecedented power and ingenuity and that we need to be prepared. The anthrax that was sent to Congress had enough anthrax potential to kill 100,000 individuals, if it was used properly and, therefore, we have to be protected. We have to protect the American citizens.

We have already done a great deal. Today the United States is better prepared than ever to meet the threat of terrorist attacks with a biological, chemical, radiological or nuclear agent, and I would hope that you would once again come over and see it. I am confident you would come away from that with a lot of your fears allayed that we could respond very quickly in America.

The national stockpile of medical countermeasures is large and getting more extensive all the time. We have 12 strategically located sites, 50 tons of medical supplies and equipment, antibiotics and so on in every one of those sites, and we can move those within 7 hours to any city in America. It requires 9 semi-truckloads or 1 KC-135 to do that. But the stockpile may not be enough, unfortunately.

The medical treatments available for many pathogens have improved little in decades. The smallpox vaccines available today hardly differ from those of the 1960's, in fact are the same almost. Some treatments for radiation and chemical exposures have not changed much since the 1970's, and some diseases such as ebola have never had any effective medical countermeasure.

These diseases lack effective or modern treatment in part because they are rare. By contrast, the treatment of the vast majority of common, naturally occurring illnesses has improved dramatically as a result of continuing innovations from biomedical research and development. Heart attacks, for instance, were often fatal in the 1970's, but they are much less so today.

Better detection and therapeutic options have significantly improved survival rates for many kinds of cancer over the last years. We must bring that sort of progress, ladies and gentlemen of this committee, to the rare yet deadly threats posed by bioterrorism and by bioterrorists.

That is why President Bush announced Project Bioshield. It would spend roughly \$5.6 billion over 10 years on new countermeasures to prepare America for a bioterror attack. This proposal would be able to speed up the research and the approval of vaccines. You will be able to see the concept, the current law, and the Project Bioshield, how much more we can accelerate it if, in fact, we are able to get Project Bioshield through.

This proposal would speed up that research and approval of vaccines and treatments and ensure—this is one of the most important parts—ensure a guaranteed funding source for their purchase. That is why it is mandatory and not discretion.

Just the latest in our forward looking efforts in order to protect America's homeland: For example, the President's budget foresaw and also prepared for an influenza outbreak. Pandemic flu in 1918 caused 500,000 Americans to die. It proposes under the President's budget to spend \$100 million to ensure the Nation has an adequate supply of influenza vaccine in the event of pandemic. We were not prepared for that, and we still have a long ways to go in order to get prepared for a pandemic flu.

Due to the constant changes in the circulating influenza strains, we cannot stockpile influenza vaccine, and the current manufacturing methods do not meet the Nation's need in the event of pandemic. For instance, we use the old procedure of developing flu vaccines using eggs, but an avian flu strain would kill the eggs which would prevent us from creating the flu vaccine. So it is important for us to come up with a new cell kind of vaccine.

Funds will be used for activities to ensure a year-round influenza vaccine production capacity in the development and implementation of rapidly expandable production technologies. We will work closely with industry to accomplish all of these goals.

The bill before you today, Mr. Chairman and members, the Project Bioshield Act of 2003, has three main parts. First, it would give the department, working through NIH and the National Institutes of Allergy and Infectious Diseases run by the famous Dr. Tony Fauci who I believe is one of the paramount scientists in the world and is with me today. He will have new authorities in order to speed up his research and be able to allow him in his development phase to promising areas of medical countermeasures against potential bioterrorism agents.

Second, it is going to allow us to create a permanent indefinite funding authority, because we need that in order to be able to tell a company that we are the only ones that are going to buy this. There is no other market out there to buy plague or botulinum toxin vaccines. We are the one, and we will have the money in order to purchase. We will enter into a contract to purchase that from you. Then, of course, we can also put it in the inclusion in our strategic national stockpiles.

Third, and this was described very aptly by Chairman Tauzin, in a national emergency the bill would allow me to suspend the full lengthy FDA approval process if a product in the approval pipeline is absolutely urgently needed and has great potential to protect, diagnose, treat or prevent a serious disease caused by a bioterror agent.

In other words, Mr. Chairman and members, we would use NIH to push research through the process and our procurement authority to pull the treatment into the stockpile.

I look forward to discussing all three parts of the bill. The President has made improving our Nation's health and health care one of his biggest priorities for this year. By working together—and I was just very excited to hear the bipartisan kinds of remarks made by members of the committee today, wanting to work to improve

the bill, and I would like to say in conclusion, we want to work with each of you on a bipartisan basis to come up with the best bill possible, because we are all in this together, in order to protect America.

I thank all of you for your dedication, your leadership, first on the bioterrorism bill and also on health issues, and now, of course, this very important issue in front of us today. Thank you, Mr. Chairman, for giving me this opportunity.

[The prepared statement of Hon. Tommy G. Thompson follows:]

PREPARED STATEMENT OF HON. TOMMY THOMPSON, SECRETARY, DEPARTMENT OF
HEALTH AND HUMAN SERVICES

Chairmen Bilirakis, Shadegg and Members of the Committees, thank you for inviting me here today to discuss the Administration bill, Project BioShield Act of 2003. As you know, the Department of Health and Human Services has been heavily engaged in the Federal government efforts to prevent, prepare for, and respond to acts of terrorism, particularly those involving chemical, biological, radiological and nuclear threat agents. This bill is a continuation of such efforts. It would enable the Government to develop, procure, and make available countermeasures to chemical, biological, radiological, and nuclear agents for use in a public health emergency that affects national security.

Pharmaceutical research and development historically has focused on development of products likely to attract significant commercial interest. Many countermeasures for potential agents of terrorism realistically have no market other than the government and thus have not generated a great deal of manufacturer interest. Because the market for developing countermeasures is speculative, without government interest, private companies have not invested and engaged in developing the countermeasures that the current situation warrants. However, in the vaccine development area, representatives of the pharmaceutical industry have stressed that, to the extent that the federal government can define its vaccine requirements and assure up front that the requisite funds will be available to purchase the vaccines, the industry will meet the challenge.

In these post-9/11 times of increased potential for chemical, biological, radiological, and nuclear and other terrorist attacks, it is important now more than ever for the United States to take all necessary steps to protect its citizens from these agents. The current security environment dictates the need for rapid acquisition of countermeasures. Armed with technology that only recently was the stuff of science fiction, the U. S. armed forces are better equipped than ever to take military actions against threats to our national security and defend U.S. citizens against missiles, aircraft, guns and other traditional weaponry. But other not-so-traditional threats are lurking. Our enemies seek, and in some cases have already obtained, the ability to acquire and manipulate biological, chemical, and nuclear weapons that could penetrate our military defenses and civilian surveillance systems, and cause significant harm. We need your help to confront these threats to our homeland.

The possibility of the intentional use of chemical, biological, radiological, and nuclear agents presents a true threat to our society. You have heard about many of these threats: anthrax, smallpox, tularemia, botulinum toxin, hemorrhagic fevers and plague. We will fight these new weapons, not with bombs and guns, but with countermeasures such as vaccines, therapeutics, and early diagnosis. We may be called upon to provide mass inoculation or drug treatment. The personnel who will lead the efforts to develop, acquire, regulate, and administer these medical tools will not necessarily wear military uniforms or be headquartered at the Pentagon. They are civilians and scientists of the Department of Health and Human Services located in such places as the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) and the National Institutes of Health (NIH), as well as State and local health officials.

We are making rapid progress in acquiring countermeasures for the agents of greatest concern such as smallpox, anthrax, and botulism toxin and have made advances in development of new products. We have sufficient Aventis smallpox vaccine to vaccinate the country in an emergency and the new ACAM2000 cell culture vaccine is coming into the stockpile at a rapid rate. We expect to have 155 million doses by this summer. NIH initiated the industrial development of a safer next generation smallpox vaccine by signing two contracts with manufacturers last month. We will have a stockpile of antibiotics to deal with an attack with anthrax, plague and tularemia. In addition, we have access to stockpile of the current anthrax vaccine

and are optimistic that an accelerated development program involving two manufacturers begun last October will result in production of a new recombinant anthrax vaccine sometime next year with Bioshield funding. Tularemia and plague vaccines are in the research phase and expected to move into advanced development in the coming year. We have acquired additional quantities of botulinum antoxins for the treatment of botulism.

Because of a relative lack of focused research on terrorist agents, the medical treatments available for some types of terrorist attacks have improved little in decades while there has been tremendous and rapid progress in the treatment of serious natural-occurring diseases. At a time when Americans must confront the realities of terrorism directed at the United States, it is imperative that the Federal government be prepared to protect our citizens from potential agents of bioterrorism.

Many of the available countermeasures have been made using traditional, older technologies, and some have significant side effects (e.g., smallpox and botulism vaccines). Newer products produced using advanced technologies such as recombinant proteins against anthrax and botulinum toxin or more attenuated viral strains to protect against smallpox hold out hope of reducing adverse reactions while maintaining effective protection. Extensive studies must be performed to assure that these products are both safe and effective. Showing effectiveness when diseases do not occur naturally can be challenging and requires the use of appropriate animal models and careful studies of the critical immune response to a vaccine. These studies are best planned with close interaction between government scientists and the countermeasure sponsors. Such early product development planning has been going on in partnership with FDA, NIH, CDC, and others (e.g. the development and evaluation of new smallpox and anthrax vaccines). Other examples where older vaccines or other technologies have been employed (often effectively) include vaccines for plague and anthrax and immunoglobulins for treating smallpox vaccine complications and botulism. Also, the promise of rapid productions of large amounts of monoclonal antibodies that could be targeted for use to protect against a variety of bioterrorist pathogens or vaccine adverse events is becoming a reality.

This must be a public and private partnership. The pathway from idea to final product is complex. The best scientific approach to identifying the best drug and vaccine candidates must be based on laboratory studies. Testing must be performed in appropriate animal models to document safety and appropriate protective or treatment response, and to help determine dosing. Human studies must be carefully initiated to assure the basic safety of the product, and then appropriate dosing and response must be determined based on measurements of levels of drug or antibody predicted to have a protective effect. Steps must be taken to assure that the materials used to make the product and the final product itself can be manufactured safely, free of contaminants, and with reproducible and predictable purity, potency, and composition. Careful trials in humans, or where not possible, animal models, must be performed to show that the product is safe and effective for the types of populations who might receive it and against the methods of infection or exposure that could be encountered. All of these steps require careful planning, experience, and ongoing management and scientific evaluation. Costs to develop and manufacture high quality biological products and perform and evaluate the needed animal and human studies are high. Grants and contract mechanisms may not always be sufficient or attract the most experienced manufacturers. Manufacturing capacity for biological products, particularly for vaccines, is not substantial. For all these reasons, the best possible support and public-private partnerships and teamwork are essential.

The President announced BioShield in his State of the Union Address. This is a key legislative priority for this Administration. The BioShield bill is designed to speed the development and availability of medical countermeasures in response to the current threats our Nation faces. The goals of Project BioShield are: 1) to accelerate and streamline government research on countermeasures; 2) to create incentives for private companies to develop countermeasures for inclusion in the stockpile; and, 3) to give the government the ability to make these products widely available quickly in a public health emergency in order to protect our citizens from an attack using a select agent. This legislation is a critical component of our Nation's homeland security strategy.

The bill has three main provisions.

EXPEDITING RESEARCH AND DEVELOPMENT AT NIH

First, the Department, working through the National Institute of Allergy and Infectious Diseases at NIH, would be given new authorities to speed research and development in promising areas of medical countermeasures against potential bioter-

rorism agents. The increased authority will provide additional flexibility in awarding contracts, cooperative agreements, and grants for research and development of medical countermeasures including vaccines, drugs, biologics, and diagnostics, and streamlined authority to hire necessary technical experts. Funding awards would remain subject to rigorous scientific peer review, but expedited peer review procedures could be used where appropriate.

NIH is leading the Federal government's campaign to improve the Nation's public health through biomedical research. The major reason that NIH has been entrusted with this vital leadership role is its proven record in combating naturally occurring emerging and re-emerging diseases, which is fortified by its rigorous system for ensuring that only the best science is supported by Federal dollars. Underpinning NIH's research is a rigorous peer review system, which brings together top experts from the public and private sectors of scientific research, as well as patient representatives and other members of the public, to evaluate research grant applications. NIH applies stringent management controls over contracts, personnel, leasing, and construction to ensure careful and responsible use of taxpayer dollars. These safeguards have served the country well. Right now NIH is leading us through the greatest era of discovery in the history of medical research.

One of the three major objectives of the President's Project BioShield initiative is to speed up NIH research and advanced development in targeted areas by providing more flexible authorities for NIH including procurement and personnel recruitment for critical biodefense work. Our BioShield proposal would authorize the Secretary of Health and Human Services, acting through NIH, to simplify and expedite acquisition requirements for material and services through such mechanisms as raising the dollar threshold for simplified acquisitions and using noncompetitive procedures when necessary. The Act would also allow the Secretary to expedite scientific peer review requirements in urgent circumstances, but still require a process of quality review.

Project BioShield is intended to strike a balance, during times of crisis, between the Federal government's need to guarantee that the best research is conducted effectively and efficiently and the national need to have a quick turnaround in responding to biological, chemical, and nuclear weapons of terror. With the authorities contained in the Act, we can improve our ability to respond to chemical, biological, radiological or nuclear attacks against American citizens and soldiers.

It often takes many months to issue research grants, engage pharmaceutical companies to manufacture vaccines and other drug therapies, hire personnel and consultants, or acquire material and services. In times of emergency, we cannot afford the time it currently takes to accomplish these goals and events. We need vaccines and drugs to fight bioweapons right now. We need expertise right now. We need to build biocontainment facilities to conduct research right now. Project BioShield gives us the tools to cut through red tape and accomplish our mission.

PROCUREMENT OF COUNTERMEASURES

Second, the Administration's bill creates a new permanent, indefinite funding authority within the Department of Homeland Security (DHS) to procure medical countermeasures for inclusion in the DHS Strategic National Stockpile. This Department will play a major role along with DHS in identifying and evaluating critical biomedical countermeasures. A great deal of work has been done to identify vaccines and antitoxins that would be needed to protect the U.S. population from dangerous pathogens, e.g. anthrax, smallpox, botulinum toxin, tularemia, ebola, and plague. In the interest of national security and public health, it is essential that the Administration engage in the process as early as possible with sponsors and organizations that are developing the therapeutics, vaccines, and countermeasures. This Department will maintain a proactive role to help ensure that the products are developed as efficiently as possible.

The Administration has already identified several products that would likely qualify as countermeasures and is meeting with sponsors to help foster the successful development of these products. Such products include new generation smallpox and anthrax vaccines and countermeasures to treat botulism, plague, ebola and other hemorrhagic diseases.

The bill requires the HHS and DHS Secretaries to identify specific countermeasures that would be appropriate for procurement and, in coordination with the OMB Director, make recommendations to the President. The following determinations must be made in order for the DHS and HHS Secretaries to make a procurement recommendation: 1. determination that the product is a qualified countermeasure (the bill defines a qualified countermeasure as a drug or biologic product that is approved or licensed by FDA or one that is likely to be FDA approved or

licensed within five years); 2. determination of quantities needed and feasibility of production and distribution; and 3. determination of no significant commercial market for the product other than as a homeland security threat countermeasure. This authority will enable the government to purchase vaccines and therapies for which no other significant commercial market exists, as soon as experts believe that the countermeasures can be made safe and effective.

The Administration has carefully constructed this system of technical determinations and processes leading to a recommendation to the President because of the extraordinary nature of the proposal for permanent, indefinite funding authority. The Administration is committed to ensuring that recommendations to use this new authority are carefully considered with input from all experts within the Executive Branch, and that the final determination to exercise this spending authority is made by the President. Any countermeasures that do not meet the criteria laid out in our bill, or that are otherwise determined not to be appropriate for procurement through this authority, may still be purchased through the existing DHS discretionary stockpile authority.

The Administration recognizes that no other significant commercial market exists for many of these products that will be needed to protect our military and civilian population. This authority will enable the government to purchase vaccines and other therapies provided experts believe that the countermeasures can be made safe and effective. The Secretary of Health and Human Services and the Secretary of Homeland Security will collaborate in identifying these critical medical countermeasures, by evaluating likely threats, new opportunities in biomedical research and development, and other public health considerations.

EMERGENCY USE AUTHORIZATION

The FDA approval process for drugs, devices, and biological products is the gold standard for the world. Sixty percent of the world's drugs are introduced first in the United States. Research and development pipelines hold the promise of dramatically advanced treatments, thanks to breakthroughs in genomics, proteomics, nanotechnologies, and other biomedical sciences. In the years ahead, we can look forward to more sophisticated, individualized, and effective treatments. Our policies and regulations help ensure that products that get to market are safe and effective. In addition to animal studies, sponsors of new drugs and vaccines typically conduct three phases of clinical trials in humans to demonstrate the safety and efficacy of a product. This process can take years, and is procedurally cumbersome. Only a small percentage of all products tested are found to be safe and effective and allowed to come to market.

In preparing for the challenges we face today, we may not always have sufficient time when addressing the threat presented by agents of bioterrorism. The current FDA approval process is too long to be used during emergency situations. We have some mechanisms in place to get products to market faster, e.g. the accelerated approval mechanism, and expedited review. The animal efficacy rule provides a new avenue for approval for products whose efficacy cannot be tested in human clinical trials. The single patient IND process and the treatment IND process permit access to unapproved products. However, these mechanisms alone are not sufficient in an emergency.

This bill will permit the Government to make new and promising treatments still under development available quickly if needed for use in emergency situations where no effective approved or licensed products are available—potentially saving many lives. This authorization will only be used when a national emergency has been declared. In the absence of FDA approval of a product for a specific countermeasure use, the BioShield bill permits the HHS Secretary to issue an emergency authorization that would provide Americans with access to certain unlicensed countermeasures. The Secretary has discretion to facilitate the availability of these important products. Before issuing an emergency authorization, the HHS Secretary must make the following conclusions:

- the agent specified in the determination can cause serious or life-threatening disease;
- the product may reasonably be believed to be effective in detecting, diagnosing, treating, or preventing the disease;
- the benefits of the product may reasonably be believed to outweigh its risks;
- there is no adequate alternative to the product that is approved and available; and
- any other criteria prescribed in regulation are met.

This bill would allow use of the best technology available at the time of a declared emergency. The emergency use authorization would remain in effect no more than one year, unless the specific terrorist threat justifies extension of the authorization.

FDA regulations are stringent when it comes to informed consent for investigational products. Because urgent situations may require mass inoculations and/or drug treatments, such informed consent requirements may prove impossible to implement within the necessary time frame when trying to achieve the public health goal of protecting Americans from the imminent danger. The legislation would provide for the Secretary to impose conditions on the authorization, either by regulation or on a case-by-case basis, where appropriate to protect public health. Specifically, the bill provides that such conditions shall include labeling and other requirements to ensure that health care professionals are informed of the special emergency nature of the authorization; of the benefits and risks (and the extent to which such benefits and risks are unknown); and of the alternatives to the product, and their benefits and risks. In addition, the conditions of authorization may include the following:

- labeling and other requirements to ensure that patients are informed of the special emergency nature of the authorization; of the benefits and risks (and the extent to which such benefits and risks are unknown); of any option to refuse the product; and of the alternatives to the product, and their benefits and risks;
- limitations on who may distribute the product and how distribution should be performed;
- limitations on who may administer the product, to whom it may be administered, and when it may be administered;
- requirements to perform further studies or clinical trials;
- recordkeeping and reporting requirements;
- requirements, or waiver of otherwise-applicable requirements, regarding good manufacturing practice; and
- requirements for monitoring and reporting adverse events.

The language of this bill is narrowly tailored to address the essential components for use of an emergency authorization. It provides specific conditions and criteria for issuance of such an authorization. It requires a declaration of emergency and provides for a limited duration of use. It gives the Secretary authority to require recordkeeping and access to records. Finally, it provides civil monetary penalties for violations.

CONCLUSION

The Department of Health and Human Services is committed to ensuring the health and medical care of our citizens. Project BioShield is another step towards enhancing our Nation's ability to respond to biological or chemical threats.

In summary, our BioShield proposal would:

- Ensure that sufficient resources are available to procure the next generation of countermeasures;
- Accelerate NIH research and development by providing more flexibility in the contracting process, procurement authorities, and grant making for critical biodefense work; and,
- Make promising treatments available more quickly for use in emergencies by establishing new emergency use authorization procedures at the FDA.

Mr. Chairman and members of the Committee, we applaud the Senate's bipartisan effort to move this issue forward and we likewise hope for your bipartisan support of this bill. We look forward to working with you to get this needed legislation enacted into law.

Mr. BILIRAKIS. Thank you, Mr. Secretary.

Mr. SHADEGG. I will start with a brief round of questions.

As I think you gathered from the opening statements, there is a great deal of consensus on the need for this legislation and its importance. However, there are measures within it that are rather controversial. I think one of them clearly was addressed by the ranking member of the Commerce Committee, the question of mandatory versus discretionary spending.

Now I would like to give you an opportunity at this point to kind of make your case for why you and the administration believe that

mandatory spending is essential for the success of this particular proposal.

Secretary THOMPSON. Thank you very much, Mr. Chairman. The reason for the mandatory is basically to create the market. What we are going to do is we are going to use NIH to be able to push the research. Research gets to a point, either intramurally or extramurally, from NIH. Then once it gets to that point, you got to establish the market. You got to be able to manufacture it.

Unless there is mandatory funding, there is less likelihood that a company will want to go through that unless they know they are assured of the money, they are assured of the possibility of having that valid contract. That is why the mandatory versus the discretion.

Second, we had discretionary money put in this past year for \$250 million for developing new anthrax. Congress in the budget appropriation bill this year took away that \$250 million for anthrax. That was a discretionary thing in Congress. I am not going to complain, but I am just pointing that out. That was a discretion. We were trying to work out a market to create that, but that was a discretion that was taken away from us in regards to creating that anthrax.

That is why we think the mandatory is much more important. If we are going to go to Company A and say to you, we are—and Company A says why do I want to put in \$100 million to manufacture plague vaccine and it may take my company 3 to 5 years to do so. Is there going to be money available? Do I want to spend \$100 million betting on Congress to authorize 5 years out a contract that is going to require \$500 million?

I don't know any company that will do that. They won't know what is going on. So there is the up-front money that they are going to have to put in, in order to get the manufacturing of that vaccine or that antiviral or whatever the case may be, and they know that the Federal Government is the only place—the only customer they've got.

So it is important for them to be assured that they are going to have it. That is why it has got to be mandatory, sir.

Mr. SHADEGG. I've got a number of other questions, but our time is limited, and I know there are other members that would like to question. So I am going to yield at this point and call on Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman. Thank you again, Secretary Thompson. You spoke articulately about the production of plague vaccine and other both preventive and curative drugs, if you will, and you talked about incentivizing the private sector, finding ways to encourage them and then we would purchase those drugs from them.

Our Nation, our military, has done it a different way or has had some alternatives that have worked over the years, too. As you know, Walter Reed has some amazing accomplishments under its belt. They have conducted clinical trials in antidiarrheal, hepatitis E vaccines as well as vaccines to protect against multiple infectious diseases.

They have done the antimalarial both vaccines and drugs better than any public or private organization in the world over the last

100 years, almost certainly. Their budget, however, is only about \$20 million. The drug industry says a new drug costs them to develop about—factoring failures into that, about \$800 million. Many of us question that number, but it is certainly multiples of the budget of Walter Reed.

Has the administration thought of putting more resources into Walter Reed? I mean, certainly NIH does an awful lot of research that has been very, very productive. But is there any thought of putting more money into Walter Reed and charging them, as they were charged with malarial—antiparasitics and malaria and vaccines? Is that something you are entertaining?

Secretary THOMPSON. We certainly would look at that, Congressman. We have the responsibility in the Department of Health and Human Services for bioterrorism, and Dr. Fauci's institute has been doing just a wonderful job.

This Congress appropriated last year \$788 million for new research on bioterrorism agents, and they are doing the basic research right now for these bioterrorism agents. Therefore, we think it is the logical place where they have already done this to put it there instead of trying to create another program in Walter Reed.

We certainly would look at that. We certainly understand Walter Reed is doing some wonderful things. We just think in bioterrorism the experts are under the leadership of Dr. Fauci.

Mr. BROWN. Dr. Fauci, would you like to respond?

Mr. FAUCI. Mr. Brown, also it should be pointed out that in the arena of biodefense countermeasures, we have years ago, and now have intensified, our collaborative interactions, particularly with U.S. AMBRD up at Ft. Detrick.

So there is a lot of synergy going on that wasn't formerly appreciated, taking advantage of the very best of what they have to offer, as well as what we have to offer is not only the kinds of things that they have been doing but a broader scope addressing a much larger and much more complex civilian population.

I think that is something that the general public doesn't really fully appreciate, that the excellent job that the Department of Defense has done has been directed at countermeasures that are for a population that, almost by their very definition, are a rather restricted, by definition, healthy population.

The kinds of problems we need to deal with go from infants to the elderly, people who are sick, people who are on medications. So that the problem is really much more complex in scope.

Having said that, getting back to my first comment which is important, that we are collaborating very nicely with them now.

Mr. BROWN. That is helpful. Thank you. Second question, last question: Talk to me, if you would, about what we are doing on antimicrobial, the whole issue of antibiotic resistance. I mean, certainly, we need to deal with nontherapeutic use of antibiotics, but are we finding a way in this Bioshield legislation to encourage the development of more antibiotics?

Scientists will say there just aren't the number of antibiotics in the pipeline. So we really need to do two things. We have to figure out ways to slow down the building of the antibiotic resistance. We also have to find ways to encourage the pipeline to be filled and

move more quickly for new antibiotics. Give us your thoughts on that, Dr. Fauci.

Mr. FAUCI. Thank you for that important question, Mr. Brown. At the NIH we, in fact, have now as part of our broad, as the Secretary described, the push toward the development of countermeasures, have a program on the development of novel antimicrobials.

I must say right from the beginning that that absolutely needs to be joined in a collaborative way with industry, because no one is going to be able to do that without industry, as I am sure you are going to hear from our industrial partners in the next panel.

The other thing is that you have antibiotics in the classic sense, but we are also looking at innovative ways to block microbes that are not necessarily the common pathway of a synthetic type of an antimicrobial. A typical example is some of the work that is going on now of using biological ways, like monoclonal antibodies, to block some of the toxins as well as to block some of the microbes themselves.

So we have a very robust program that is going to get even better now that we will have, were this passed, the capability of pushing it along a little bit more rapidly at the same time that industry can come in with the pull of getting it to happen in reality.

Mr. SHADEGG. The time of the gentleman has expired. Chairman Bilirakis.

Mr. BILIRAKIS. Thank you, Mr. Chairman. Mr. Thompson, Secretary Thompson, let's see, flexibility is an important part of this process. Emergency use authority is in the proposed legislation. I would ask a question. What would happen if the government entered into a contract with a manufacturer to develop a vaccine for the plague, but 2 years into the contract another manufacturer developed a clearly superior vaccine?

If the government wanted to then purchase the clearly superior vaccine, which I trust they would want to do, would the government still have to pay for the inferior vaccine? Now we go into vaccine. We go into contract law here, and I appreciate all that. But maybe you can respond to that. And if you think that there should be some changes made to allow you to do that without—well, go ahead, respond to it.

Secretary THOMPSON. The perfect is not an enemy of the good. In regard to that, if we have entered into a contract, the Federal Government is going to have to comply with the specificities of those particular contracts. You also have to realize that the perfect, the more perfect vaccine that subsequently comes, more than likely has been built upon the research which was in the good vaccine which we have a contract for.

We will have to purchase that, and we will have to live up to the contract, but that does not mean that we should not go out and purchase the better plague vaccine. We certainly have that opportunity to do so, but we are also going to have to comply with our contract, because we doubt very much if that perfect vaccine or that better vaccine that you are talking about, Congressman Bilirakis, would have been made without the original contract or the original research done by NIH.

Mr. BILIRAKIS. All right. Well, in the interest again of flexibility, yes, what you have said is certainly contract law. No question about that. But should there be in that definition of flexibility the government to have the right or the flexibility to not have to pay maybe for the full—under the full contract terms of the first vaccine developer? Should you have that kind of flexibility and, if you did have that kind of flexibility, would it discourage people from reaching out and doing this, knowing darn well that they might end up losing in the final product?

Secretary THOMPSON. Congressman, we set milestones. We set goals in our contracts, and we would pay for the work and the goals up to a particular point. If we saw a superior package coming, we certainly would figure out a way on how we could terminate the contract at that particular point. We would pay for all the expenses. We would probably have to pay for a profit to the company, but if we had a superior product, we certainly would look at ways in which to purchase that.

So the contract is set up so that we would ensure ourselves, but we would ensure the company, because we've got to make sure these companies will go along to get this far.

Mr. BILIRAKIS. Sure.

Secretary THOMPSON. So we put goals into our contracts and, once the goals have been accomplished, we pay for it, and then we would look at going to a subsequent contract with a superior project.

Mr. BILIRAKIS. All right. Thank you, sir. I would like to give you an opportunity to maybe expand upon your prior comments regarding liability, the necessity for liability protections in order to incentivize contractors to develop countermeasures.

Do you feel that that is such a critical part of any piece of legislation, and why do you feel that way? I think it is important that we know that.

Secretary THOMPSON. It is important. I can't think of an incident in which it wouldn't be. So I would say all companies that deal with vaccines want to be exonerated for their liability, and we do that, and there is a section in the statute that gives me the authority to give exculpatory exemptions to companies, exonerate them from their liability.

I think it is Section 8408.4. I'm not exactly sure of that, but I think that is the one it is. We have done that when we encourage the companies. Acambis—we had a contract for the Acambis1000. We also had a contract with Acambis-Baxter2000 for the production of smallpox, and we also, of course, as you know, purchased 75 million dose—82 million what it finally ended at—doses of smallpox from Aventis Pasteur, and we are going to be using that, and we had to give them immunity for liability in order to use that smallpox vaccine.

We have a general thing. We did not include it in the Bioshield legislation, but we have it in a general portion of the Federal code, and we would use that, if need be.

Mr. BILIRAKIS. Thank you, Mr. Secretary. Thank you, Mr. Chairman.

Mr. SHADEGG. The time of the gentleman has expired. It is now my privilege to recognize the ranking member of the Subcommittee

on Emergency Preparedness and Response of the Select Committee on Homeland Security Committee, Mr. Thompson. Welcome.

Mr. THOMPSON OF MISSISSIPPI. Thank you very much. Welcome again, Mr. Secretary. Taking off from the earlier question raised by my colleague, if a company feels that for some reason they have not been treated fairly in the procurement process, what options do they have under this proposed legislation?

Secretary THOMPSON. Usually they have appeal rights, Congressman Thompson, but in this case there is such a dearth of markets and such a paucity of companies that would even get into this business, we don't think that that is a serious problem. We have to use the ability for speed in order to get this particular product to market, and we are the only market.

So when we go out and we enter into a contract, we are going to have to go out and find a company, because there aren't any companies that are producing vaccines for hemorrhagic fever viruses, the plague, botulism or anyplace. So we have to create the market. So there's going to be so few companies that would even be interested in it. We have to go out and actually negotiate with them to go into it.

The basic research is going to be done under the supervision of NIH and under supervision of Dr. Fauci. They will get the research to a certain point, and then we are going to have to take that research. We are going to have to go out and get a company. There aren't going to be many companies standing in line that want to do this.

So I don't think there is going to be a reason for appeal, plus we have to use our ability to get this thing done, because if there is a bioterrorist agent that is going to hit America, we cannot afford appeal process to go on and on and prevent us to get to our ultimate objective, and that is to defend the American citizens.

Mr. THOMPSON OF MISSISSIPPI. Well, thank you. So in other words, we will make the market. We will grow the market.

Secretary THOMPSON. We are going to create the market, Congressman.

Mr. THOMPSON OF MISSISSIPPI. Fine. Now in terms of defining the market, have you at this point created in your mind how definitive you will be in identifying the market or will it be a moving target, more or less?

Secretary THOMPSON. It is going to have to be a moving target, because we don't know—we will not have the intelligence at this particular point in time to determine what bioterrorist agent that we may get hit with or we may not have the basic research.

We are doing research right now at NIH on ebola, and we feel somewhat good about the basic research that is being done. So we may take that research and get to a company to produce, manufacture the ebola vaccine or some other vaccine. So at this point in time, we don't know.

We don't know if smallpox is the one that we are going to be the most concerned about—it is right now—or is it going to be botulinum toxin or is it going to be the plague? Botulinum toxin, we still use it the old fashioned way. You have to go out and create the serum in a horse and bleed the horse to get the serum to develop the antidote. So that is a very arcane procedure.

We are looking at ways to come up with new procedures, new manufacturing, and a new way to create a vaccine for a botulinum toxin. Therefore, we are going to do the research, but we are going to have to go out and find a company to do the manufacturing, and there's no company—There is no company in the world even considering doing anything in botulinum toxin at this point.

Mr. THOMPSON OF MISSISSIPPI. Thank you.

Mr. SHADEGG. It is now my privilege to call on the chairman of the full House Select Committee on Homeland Security, Mr. Cox.

Mr. COX. Thank you, Mr. Chairman, and thank you, Mr. Secretary. Thank you both for being here today.

As you know, the Committee on Homeland Security and the Energy and Commerce Committee both are anxious to move this legislation because of the urgent national need, and we intend to do that for you. We are having this hearing on a joint basis to make sure that we expedite the process and that we don't make you come up here multiple times to give the same testimony before different House committees.

We had a chance to talk about this earlier down at the White House, and since that time I have been very focused on doing everything that we can on the Homeland Security Committee to make sure that we enact this into law for you.

Let me ask a couple of questions that remain cloudy for me. First, with respect to the taxpayer investment for the development, for example, of a serum. I believe, having read the draft statute, that you would have authority in letting these contracts to negotiate an ownership piece for the government of any commercial application for the serum or toxin antidote, or whatever it is that you are seeking to have developed, in your discretion, and presumably also that you would have the opportunity to negotiate that for any research by-products that were funded with taxpayer dollars.

Is my legal understanding correct, No. 1? No. 2, is that likely to be your intention?

Secretary THOMPSON. To answer the first one, yes. The answer to the second one, I haven't even decided. I haven't even discussed it with our lawyers or anything. We would have to discuss that with you and other members of the administration, other members of this committee and Congress, but at this point in time we haven't even given any thought to that, Congressman. We probably should have, but we haven't.

Mr. COX. The second: With respect to the funding mechanism of a permanent indefinite appropriation, in response to questions from the panel here today concerning why this should be mandatory—in fact, I think it was Chairman Shadegg that put the question to you—what I understand is that first we are going to have to create this market from essential nothingness. Second, we want to make sure that the vendors are themselves assured of monies down the line. These contracts are up to 5 years and can be extended through a valid contract. Third, that because the Federal Government is the only customer, there can be no question about our reliability, and it should not be subject to political reversals down the road.

If the legislation meets all of those criteria, will that satisfy the objective?

Secretary THOMPSON. I certainly believe so.

Mr. COX. So if we can find a way that is essentially tantamount to a permanent indefinite appropriation but does not technically create the first national security entitlement program in the history of the country, but meet all of these objectives, that is the main object. Is that correct?

Secretary THOMPSON. That is. We have looked at so many different examples. We felt that this was the best way to accomplish all of the objectives, Congressman. But we want to work with you, and we know the importance of Congress having the ability for oversight, and we want to work with you in developing the best bill possible. But we think the permanent mandatory kind of an appropriation accomplishes the best and the most flexible and the most expedited way to do that, and that is why we went that route.

Mr. COX. Let me explain just a portion of my concern. I have every confidence in you as Secretary. I have every confidence in the Department. I have every confidence in Secretary Ridge. I have every confidence in the President, and I have every confidence in subsequent secretaries and presidents to make correct decisions when it comes to protecting our country from terrorist attacks of this type.

A permanent indefinite appropriation creates a program with eternal life, and down the road, even if it is the discretion of the president or the secretary or someone else to move on to some other priorities, this program is going to gain, if it were structured that way, a life of its own. I want to make sure that we don't tie the hands of future secretaries and future presidents by crowding out what may be the national security priorities of the future.

That is one of the reasons, one of several reasons that I am concerned about that particular structure, but I have a complete understanding of the need to convince not you or me but third parties in the private sector that they want to put their money and resources into this, and that the United States can be counted on to fulfill its side of the bargain.

So if we are going to give you this legislation, I think we have to meet all of these objectives.

Secretary THOMPSON. My only rejoinder is that we definitely have to have that appropriation mandatory, because that is what the companies are going to look at. They are going to want to make sure that, if they spend the money—and as Congressman Brown says, which is the rule of thumb, it costs \$800 million to produce a new drug and get it to market. Vaccines where there is no customer at the end except the Federal Government, then you are going to have to have some sort of mandatory payment, mandatory funding source, that that company will look at it and say, yes, I am going to put the up front dollars in here to create this vaccine, knowing full well that my only customer is the Federal Government and knowing that the government has got the money there to pay me when I get the vaccine or the medicine ready to be used.

Mr. COX. Mr. Chairman, if I might, just one last question. It was my understanding from the presentation at the White House that, if we go this route and if it is structured as a permanent indefinite appropriation, that it is also unlimited in amount in any fiscal

year. That is to say, the amounts that the administration could commit are infinite in each year.

Secretary THOMPSON. That is correct, since we don't know.

Mr. COX. Thank you, Mr. Chairman.

Mr. SHADEGG. The time of the gentleman has expired. let me call now on the ranking member of the Select Committee on Homeland Security, Mr. Turner.

Mr. TURNER. Thank you, Mr. Chairman. Secretary Thompson, first of all, I think it is important for us, as I have heard the discussion—we are many members, and you have referred to this as mandatory spending as compared to discretionary. I think it is important to understand that what you have proposed is very far from the common understanding of mandatory spending, which is programs like Medicare where we are basically providing a benefit to whoever shows up and is eligible for that.

I would say that, to my knowledge, the Congress has never granted the authority that you are requesting in any circumstance, other than a very limited amount that is under jurisdiction of the Intelligence Committee, which your proposal in terms of cost would dwarf what I even understand to exist there.

I think there is—and I would hope you would be able to provide the committee with an analysis of how you arrived at the approach that you are advocating today, because in my view, there are two ways to accomplish the objective. One is what you have suggested.

The other is to provide government funded research dollars either to the private sector or to do the research internally, and then once the successful vaccine is discovered to then procure that through government purchases from the private sector or, in fact, to do it through government labs with private contractors in those labs, as we do in some instances now in the military.

If we are truly concerned about getting this job done quickly, it seems to me that a Manhattan Project type approach to it that would utilize government funded research and government funded production would be perhaps the superior alternative, because if you advance contract to a given private company to develop and then produce by guarantying them a market, you may in fact stifle the innovation that, as some member—I believe it was Mr. Thompson—suggested, that if you grant a contract to one company and perhaps another comes up with a better vaccine, then you have already committed to spend the money on the inferior vaccine and we have wasted a lot of money.

In truth, it may be that that second company may have absolutely no incentive, once they learn that you have made the contract with the one company for the long term production of that vaccine you hope they will be able to produce.

So I think that the only advantage that I see to the proposal you have put on the table is that it avoids the somewhat painful problem that we all have around here, and that is the other alternative would require us to spend some money now. So it is perhaps attractive to say we will give somebody an advance contract that we won't have to pay for, for 3 or 4 or 5 years, so we don't spend any money now. But I think we may, in fact, discourage alternative research. We may in many ways lessen the standard of care that will be used to develop the vaccine because of the limitations of liability

and the fact that the source you contract with will know they are the sole source.

I think it may be improper to base this proposal on what is, in fact, a false assumption, and that is that privately funded research and production is superior to government funded research and production.

So I would like to see the analysis that led you to the conclusion that the proposal you made is superior to the other alternative I suggest, and I would hope this committee would also conduct an independent study along those lines before we pass this legislation.

Secretary THOMPSON. Congressman, I am going to respond as Secretary. Then I am going to ask Dr. Fauci to respond as the scientist.

I have been there now 2 years, and running the Department of Health and Human Services, and 9/11 came and we started working before 9/11 on bioterrorism preparation in the department, but we were very ill prepared. We are much better today. We can respond to just about anything.

Anthrax came a couple of months later after 9/11, and we still have only one company, BioShield, that is making the anthrax vaccine. We know that there are some terrorists out there that are working on botulinum toxin, which is very lethal, could cause tremendous problems if it got in the food supply in America. There is no anti-toxin except an old procedure of developing serum from bleeding horses, and it is very time consuming. Nobody is doing it. We have no market for it.

We have really no market for smallpox except for the market that we created when we went out into the market and requested proposal and got some companies to do it, and it came up with Acambis-Baxter2000. We have no research being done, or very little research being done on the plague, and the hemorrhagic fever viruses—the only one that is really being done is ebola, but there are several other—There's 3 other hemorrhagic fever viruses that need it.

There is no market out there. So what you have to do is you have to create it. I don't see a company spending money doing private research on things that there will be no in customers except the Federal Government, and that is why we decided. It was quick. It was reliable. We could direct it. It is necessary, and that is the reason we came up with Bioshield.

I understand the Manhattan Project. I understand the private research, because I am a big believer in that, and we primed the pump with private research using NIH dollars, but in this case we haven't been able to prime the pump because there is no in market. That is why it is important to go to a concept like Bioshield in order to get it done.

Mr. FAUCI. Congressman, just to amplify on that a little, we have some very real life experiences over the last couple of years in the arena that you are suggesting. There is no doubt that, when a pharmaceutical company wants to and sets their sight on something, the resources and capabilities from the creative research right up to their unparalleled capability of driving something to a product, is something that everyone recognizes.

The difficulty that we find is that you made the comment about squelching creativity. The creativity is there. They are just not going to apply that creativity to the direction that the country needs, because they have so many other competing interests that are essentially guaranteed profit margins for them.

We will continue to intensify the push part of the creativity, not to say that is going to replace at all the extraordinary creativity on the part of the companies, but we have had situations that I think can fall into two broad categories.

The first category would be if a company is going to go this direction anyway, and we have examples of that, and they say, you know, we have a great idea, we put our own money in it and we are actually going along pretty well. We are getting ready to go to the next step of advanced development, but we need to convince our stockholders, we need to convince our board that, if they are going to put another \$100-some-odd million to give us a new plant or what have you, we've got to come to them and say we have some assurances that at the end of that process somebody is going to buy it.

Now if they come to us now, which they have, and say this is what we have, the only answer that we can give them is that, if the product is going to be ready by the year 2006 or 2007, we would like to tell you that we are going to be able to buy it, but it is going to be totally dependent on the vicissitudes of the discretionary appropriations process. That is what happened with the \$250 million with the anthrax now.

Mr. SHADEGG. Doctor, excuse me. The time of the gentleman has long since expired. So you can wrap up.

Mr. FAUCI. I'm sorry. That's it.

Mr. SHADEGG. The gentleman from Connecticut.

Mr. SHAYS. I will yield my time to Mr. Norwood.

Mr. SHADEGG. Mr. Norwood then.

Mr. NORWOOD. Thank you, Mr. Shays. That is very nice of you. Mr. Secretary, I really do appreciate you being here. Chairman, I appreciate the hearing, and basically I am thankful to you and the President for Project Bioshield. I think we are going in the right direction. It appears to me we will give you the legislative language you need in a bipartisan fashion. It is just a matter of time.

Because of that, I am going to ask a little bit of a tangent question here. I didn't get the answers I wanted to hear when it was probed just a little bit earlier. I am very concerned about what can be done to produce new products to fight naturally occurring infectious diseases.

The reason I am a little concerned is I know how focused we all are on bioterrorism, and that is precisely right. That is what we should be, but naturally occurring infectious diseases, as you know, are the third leading cause of death in America and, in fact, the second leading cause of death worldwide.

New antimicrobials, vaccines, and diagnostics are urgently needed to fight a very long list and often life threatening microbes, including those that cause meningitis, pneumonia, skin and bone infections, tuberculosis, malaria, hepatitis. You know the list. It goes on and on.

Of greatest concern, research into and development of new antibacterial drugs appear to be, from what I am hearing, at a standstill as companies withdraw from this market due to low return on investments. Now I understand the primary research, the basic science, often is applicable across several areas. We can do both things, in other words. But I am concerned that, as we focus on developing new products to fight bioterrorism, and we should, we may—underline may—be missing a public health crisis that already is occurring in United States hospitals and communities, particularly as antimicrobial drug resistance is sort of exploding out there.

For example, the FDA didn't approve one drug last year for antimicrobials. I would like just to get on the record and get your feeling about what we are doing in parallel with bioterrorism in terms of antibacterial.

Secretary THOMPSON. Thank you very much, Congressman Norwood. We have a huge program at NIAID which is run by Dr. Fauci for naturally occurring emergency infections, and I would ask Dr. Fauci to give you the exact dollars. We are not in any way giving up our public health initiatives at NIH. We are spending a lot of money, more money than ever, and I want you to know that, and we've got a great program developing.

Mr. NORWOOD. You are saying to me you do recognize that this is a problem as well as bioterrorism?

Secretary THOMPSON. Absolutely.

Mr. NORWOOD. Dr. Fauci, you want to comment?

Mr. FAUCI. Yes. Mr. Norwood, in fact, the way we look at the scientific component of it is that we have a big program, what we call emerging and reemerging diseases. From the scientific standpoint, a deliberately released microbe is just another form of an emerging and reemerging disease.

So a lot of the expertise that we have now been building up for biodefense is naturally the brain power that could be applied clearly at something like SARS, which we are dealing with right now, the possibility of pandemic flu or a variety of other issues. So that is very, very high on our radar screen, naturally occurring emerging and reemerging diseases.

Mr. NORWOOD. Well, is there any stimulus of the private sector to do a little better job perhaps in working in this area and searching for new antibacterial drugs? Are you talking to them in the sense that, hey, there is a problem brewing out here? I don't know for sure how big it is, but I know it is getting bigger.

Mr. FAUCI. Indeed. In fact, as I mentioned just a little while ago, earlier, that the whole question of developing better antibiotics for emerging antibiotic resistant or antiviral resistant microbes is something that, by definition, has to have high industry involvement, and our program clearly is aimed at synergizing with industry in that.

Mr. NORWOOD. So you feel you as an agency are doing a good job in this area, and things should get better?

Mr. FAUCI. I believe we are doing a good job, Mr. Norwood, and I believe we can do better, and will.

Mr. NORWOOD. Please do. Thank you, Mr. Secretary. Mr. Chairman, I yield back my time.

Secretary THOMPSON. Thank you, Congressman Norwood.

Mr. SHADEGG. The Chair calls on Ms. Harman for 5 minutes.

Ms. HARMAN. Thank you, Mr. Chairman. In the interest of letting others ask questions, I am only going to ask one to Secretary Thompson.

I know you agree with me that the threat of a bioterrorism attack is real and now. Passing this legislation, perhaps in an improved form, will give us more tools for later, but now is when we face a very active threat. There is another article in today's Wall Street Journal about aid to Iraq from Russia, and there were reports earlier in the week about al Qaeda's capabilities of which we were not fully aware, all of which support my view, with which I think you agree, that the threat is now.

So my question is about your current capabilities to deal with the threat. I specifically would like you to address three of them.

First, how far along are you with syndromic surveillance, this ability that you have or are developing to learn about what is going on in any hospital, in any public health facility in the country, and be able to coalesce that information in real time so that you can see, for example, if a smallpox virus has been introduced in three different locations in the country? That is one.

Number 2, how well are you doing with WMD simulations? My understanding is that Walter Reed has a facility for WMD simulation that is state-of-the-art but that health responders, first responders, have not been given access to it. I think that simulations are a very helpful learning tool, and I am just wondering about that.

Finally, how well are you doing with public education? I mentioned that in my opening remarks. I just want to commend something I just saw, which is a pamphlet prepared by AdvaMed. I gather Johnson & Johnson will talk about it in the second panel, but this is a pamphlet that is intended to be a guide for local emergency response planners on how to get medical supplies. This is the kind of thing I hope we are beginning to see, so that in our hometowns people have better information about what specifically they are supposed to do. Thank you.

Secretary THOMPSON. Thank you very much. Let me go from third, second, first, and probably ask—

Mr. SHAYS. It was just one question.

Ms. HARMAN. It is one question with three parts, and I am finished. Thank you very much, Mr. Shays.

Secretary THOMPSON. Information: We are doing a great job. Our health alert network is hooked up right now with 85 to 88 percent of the State and local health departments in the country. It will be at 90 percent by the end of the year. We are up to over 200 laboratories through our laboratory network system, and we have put out weekly notices.

I have frequent calls with all the State health directors telling them what is going on in regards to that. Julie Gerbadine is doing a wonderful job at CDC getting information out. MMWRs go out every Friday with new diseases, new information, new technology.

If a disease would show up dealing with smallpox in any particular hospital and people don't know how to diagnose it or what, they would send a lab specimen into the State lab and at the same

time send a corresponding specimen to the lab at CDC. We would immediately fly some of our epidemiologists to that hospital to work in conjunction with the emergency workers and emergency doctors treating that particular disease.

We would have the State health department. We would make a confirmation by CDC. We would also be able to strategically send and deploy extra medical personnel. We got the country divided into 10 regions. We could send up to 8,000 medical personnel to any particular region, but they are divided up into regions. We got the DMATs-1, -2 and -3. Our most sophisticated teams are 28 DMAT-1 teams. We have 2800 individuals in that.

Second, in regard to exercises, we happen right now to be having an exercise going on at the Humphrey Building as we speak dealing with food poisonings and food pathogens. We do a lot of exercises, and I would ask you to come down and take a look at our command headquarters.

In regards to our GIS system, which goes to your first question, we are the only computer base, I believe, Congresswoman, that has every hospital, every street, every railroad, every fire station, every police station, every first responder in a computer base. We can call up any city in America, determine a plume on any chemical or any bioterrorism agent, and determine what portion of the people should be evacuated.

We have every hospital listed. We know every single day the occupancy in any hospital in America, what the frequency is, and what the bed vacancy is. So that capacity is already built into our GIS system. I would love to have you come over and explain it to you. I think you would walk away from it saying, wow, they really have their act together.

Ms. HARMAN. I appreciate that answer. Thank you, Mr. Chairman.

Mr. SHADEGG. The time of the gentle lady has expired. The gentleman, Mr. Shays, for 1 question with as many subparts as he wants in 8 minutes.

Mr. SHAYS. Let me first say I am delighted the gentle lady asked her question. She truly is an expert on this issue, and it is a very important series of questions. I also want to say that I am grateful to be in a room with so many other people who have such expertise like Curt Weldon and others who have been on this issue well before you were ever Secretary.

First, Mr. Secretary, thank you for what you are doing. Your information and control center is truly impressive, and I think it will prove to be very helpful in the years to come.

I have this concern that we are straining out gnats and swallowing camels, frankly. I think that, when I wonder how we utilize our resources, I happen to believe that putting more resources into WHO and to analyze how we can improve them would be better in some cases than the fortune that we will be spending potentially in this area.

Let me say to you I also feel like picking the right vaccine is a huge gamble. I feel it is like a multi-billion dollar crap shoot. It is something like Russian roulette. It strikes me that the terrorists are just going to do what we didn't do, and I am concerned with the altered biological agents that we will have no antidote for.

How do you set R&D priorities when you know the terrorists will just shift their attention to the agents you don't fund?

Secretary THOMPSON. First, let me thank you for coming over and seeing the command center. I was very impressed by your knowledge and always have been, Congressman, and thank you very much for your dedication.

I would ask Dr. Fauci to answer that question, because Dr. Fauci is the one that really determines the research.

Mr. FAUCI. Thank you for the question, Mr. Shays. Obviously, we will never be sure that we have covered all the bases when it comes to the research priorities, but what we try to do is match what intelligence we have, ranging from things that we know have been made and have been identified such as materials from the Soviet Union and materials that were found in Iraq in the first Gulf War. That is how we came up with the category A agents, but there are others involved there.

Mr. SHAYS. You have 57 potential.

Mr. FAUCI. Yes.

Mr. SHAYS. You have done anthrax and smallpox, but you've got a ways to go.

Mr. FAUCI. Yes. Well, yes, we do have a ways to go, and we are trying as best as we can to rapidly fill in the gaps of those what we consider probability plus impact. There are a number of agents, for example, that are on our B and C lists that are important agents that would not necessarily have a devastating public health impact but are things that would be disruptive. We wouldn't be able to develop a vaccine or necessarily a therapy, although we have many therapies against many of them, against each and every one of them.

What we try to do as best as we can, a balance between the threat assessment, the scientific opportunity—

Mr. SHAYS. I get the gist. Let me ask you this. Are we moving in the direction that DoD seemed to be moving in, and that was, instead of an all hazards protection—in other words, the protective gear—they began to say let's inject an anthrax vaccine, and let's take each one, and by the time we are done we have a human being who has 10 or 15 or 20 or 30 different shots in them. Are we moving in that direction or is our hope just to have these vaccines available and to contain them and only do those who need them?

Mr. FAUCI. The latter.

Mr. SHAYS. Okay. Let me ask you this. Didn't the DoD try the non-market vaccine development with the joint vaccine acquisition program where they spent \$300 million?

Mr. FAUCI. I am not sure I can answer that adequately, sir. I don't know the answer to that.

Mr. SHAYS. My sense is that they did. They spent \$300 million, and this strikes me as somewhat of a duplication. I'm not sure that we have gotten anything back on the \$300 million we spent. Is there anyone in your department that could respond to that?

Secretary THOMPSON. It is my understanding they are working and may have developed a tularemia vaccine, but I can get that information.

Mr. SHAYS. All right. Let me just ask this last question. Will Bioshield have any greater success in actually finishing development of a vaccine than what is tried at the joint vaccine acquisition? I gather this is something you have not focused in on. I would just suggest that we do.

The DoD sometimes does things. They don't let a lot of people know about it or they do, but nobody pays attention. But a lot of failures over there. At the very least, we could learn from those failures. Thank you.

Secretary THOMPSON. Thank you, Congressman.

Mr. SHADEGG. Thank the gentleman, and the Chair calls on Dr. Christensen.

Ms. CHRISTENSEN. Thank you, Mr. Chairman. I, too, want to welcome the Secretary and Dr. Fauci. By way of an abbreviated opening statement, I want to say for the record that, you know, while we are looking at Project Bioshield and while research and development of these countermeasures is of vital importance, I think that early in this process we really need to focus on the broader issues of furthering public health security, which is my primary concern.

I think we have deficiencies in our public health system that are still unaddressed, with the impact of rising health care costs due to our lack of focus on prevention, and ensuring that everyone has equal access to quality health care, with the system's continued deterioration and with closing safety net hospitals all around the country. I think that the public health infrastructure is really in need of a lot of attention.

Therefore, even if we had all of the wonderful vaccines, medicines and different devices that are considered, that we are talking about today, I am not sure that we wouldn't be stymied by the lack of the system's ability to really get out there and delivery these, despite what you have said about the systems that you have.

So I hope that we will also, Mr. Chairman, spend an appropriate amount of time on the nuts and bolts of public health security, because it takes upwards—5 years if what we are talking about, but some experts estimate 10 to 15 years to develop new vaccines and therapies, and we can't wait that long. We have to protect our population now. So I'm hoping that we will be able to do that.

On this particular bill, though, I have some of the same concerns about the open-ended funding, the chasing after vaccines when our adversaries are continuing to develop new and perhaps undetectable and other agents that we would not be prepared to have vaccines for. But I wanted to ask the first question relating to the territories.

You mentioned, I think you said it was a GIS system that is in place that could look at any city and what is happening there and begin to respond. Does that extend to the territories as well?

Secretary THOMPSON. We haven't got to the territories yet.

Ms. CHRISTENSEN. Okay, because we have some issues there. I hope that in very short order—

Secretary THOMPSON. But I would like to say in regard to the territories, Dr. Christensen, because when I was Governor I worked very closely with all the territorial Governors. When I came in, we have sent out \$1.1 billion last year to the States and to the terri-

tories for building the infrastructure, the local State public health systems.

My only concern is that they haven't drawn down all of their money last year, and we have an additional \$1.5 billion to send out, and we are in the process of sending that out now. WE will be sending 20 percent of that money out very quickly, and then we will be asking them to show what they have done with the past installments and what they are going to do with the other.

I would encourage you to—

Ms. CHRISTENSEN. I sure will make sure that they spend their money, not only in my territory but the other territories. But the same is true for the Native American reservations?

Secretary THOMPSON. That is correct.

Ms. CHRISTENSEN. That you are able to detect what is happening there at any given time and—

Secretary THOMPSON. Yes, in America. But we haven't got the GIS system—we are working on it for the territories, and I would encourage you to come over and see what the potential is.

Ms. CHRISTENSEN. Okay. I will. Thank you for the invitation.

Secretary THOMPSON. In regards to prevention, you couldn't find a stronger advocate than me. I could speak all day on prevention and why we have to go that way.

Ms. CHRISTENSEN. Thank you. Bioshield allows—I want to ask about the approval process. Bioshield allows the government to take possession and pay for an unapproved product. Once the government has done this, there is no real incentive for the product vendor to follow through and get FDA approval, as I understand it, especially since this is something that would be used based on an emergency authorization under Bioshield.

In the interest of protecting the public, wouldn't it be best for us in this bill to require a contract for the procurement of a countermeasure to include a term that the product vendors seek FDA approval even after that emergency approval, and that the licensing or clearance for the product and a timetable for development of that approval be included in the contract?

Secretary THOMPSON. There is no reason why not, Doctor. The truth of the matter is we would only use it when there has been a declared national emergency, there is no other approved effective countermeasure, and the threat is serious and life threatening disease, and I determine that the benefits used in the product outweigh the associated risks. It's got to be immediate.

We have to—I mean, if we have a bioterrorist attack and we have something in the pipeline that may be able to prevent deaths, I got to make that determination. But after that, subsequent to that, there is no reason why they can't go ahead and go through the procedures and develop the efficacy as well as the safety.

Ms. CHRISTENSEN. Don't you have the authority to extend that emergency, just on your own, to extend that emergency beyond that time?

Secretary THOMPSON. Once the emergency is over, it goes away.

Ms. CHRISTENSEN. Well, I think that it would be best to include those protections.

A follow-up question on FDA. I recently became aware that FDA isn't really required to test on minorities, people of color. Is there

anything in this, since these vaccines, devices and therapies are going to be used on people across the country, that requires that they be tested in minorities?

Secretary THOMPSON. This emergency would not allow that. We would have to move so quickly that we wouldn't allow for the testing, Doctor.

Ms. CHRISTENSEN. Okay, something else to look at. I have heard—

Secretary THOMPSON. If I could just respond. I mean, the emergency is immediate, and—

Ms. CHRISTENSEN. I understand, and you have to weigh the risks versus the benefits, but to the extent—I still feel that, because there is a possibility of extending that emergency period, that there still should be—Even though you have approved it—

Secretary THOMPSON. That period is 1 year, and we would be doing a lot of—if the immediate emergency is over, we would do a lot more testing.

Ms. CHRISTENSEN. Okay. Well, basically, that's what I am getting at, that there still should be some safeguards in place.

Is there any role for universities in terms of the research?

Secretary THOMPSON. Oh, absolutely.

Ms. CHRISTENSEN. Because I didn't read that.

Secretary THOMPSON. Well, that is going to be the push part of it. That is what Dr. Fauci can talk more elegantly about than I can.

Mr. FAUCI. Over about 90 percent or 89 percent of all of the research that occurs out of the funding from that initial part of the push is actually executed in the academic setting and some in the industrial setting. So the universities are a major part of this.

Ms. CHRISTENSEN. Thank you. Just one last question, if I can sneak this one in. As I understand it, the Secretaries of the Department of Homeland Security and Health and Human Services collaborate in identifying the critical medical countermeasures. How do you envision both Secretaries collaborating in determining the specific threats that require the countermeasures?

Secretary THOMPSON. Homeland Security's Secretary would have to declare that there is an emergency, and he would declare that there is a threat and determines which agents present a material threat to the United States. I would have to assess the consequences of that threat, determine the agents for which a countermeasure is necessary.

Then I would have to determine the countermeasures necessary for agent, and also I would assess the availability and appropriateness of specific countermeasures to address it, and then we would have to—Then I would have to determine a specific countermeasure. Then we would take that information to the President of the United States collectively.

Mr. SHADEGG. The time of the gentle lady has expired. The chairman now calls on the vice chairman of the Subcommittee on Emergency Preparedness and Response, Mr. Weldon.

Mr. WELDON. I thank the chairman. Mr. Secretary, thank you for being here and, Doctor, thank you for joining us. I appreciate your leadership. I am here as a member of the Homeland Security Com-

mittee, but these have been issues that have been important to me my entire life, as it has with my colleagues here.

My first question builds on what Jane Harman said. That is: The bill that you proposed before us, I think, is a good beginning and a discussion point. I think there are some questions we have to deal with on the financing issue, but I think it is a good foundation, but there are some areas that I think we have to address which are not covered by the bill, and perhaps won't be covered by the bill, but they are equal challenges relative to security for the Nation from the threats of weapons of mass destruction.

The first is proliferation. The reason why we have a threat today is because of the technology that proliferated out of a destabilized Soviet Union. In 1998, 1999 and 2000, I brought Dr. Alexi Yabelkov to this Congress, and he testified that, in fact, the Soviet Union developed over 50,000 metric tons of chemical weapons, and he warned us back then we weren't taking the threat seriously enough.

In 1999 I brought Dr. Kanalbegov who wrote the book "Biohazard." He testified as the former deputy director of the Soviet agency Biopropat that we were not taking the threat of biological weapons seriously enough.

The bulk of the weapons and threats that we are dealing with now came out of the Soviet Union. Iraq did not have indigenous capability to develop chemical and biological agents. In fact, during the 1990's I documented 19 times—18 times we had evidence of illegal technology flowing out of Russia to Iran, Iraq, Syria, Libya and North Korea. Of those 18 times, at least 6 of them involved chemical precursors and biological technology.

We imposed the required sanctions 6 times out of 18. That is totally unacceptable. Just recently, we have learned that again Russian entities are illegally assisting Iraq with their weapons of mass destruction program. So I would say to the administration, not to you in particular, an equal part of this battle has got to be reinvigorate the regimes associated with controlling proliferation.

It is good to deal with the antidotes and vaccines, but let's eliminate the threat in the first place, the development and transfer of those very dangerous technologies from Russia and the former Soviet states.

A second issue involves detection. I went down to the Centers for Disease Control in the fall of 2000, and thank goodness you have changed the mindset there; because when I was there and I asked the question about how we know if a chemical or biological attack was occurring, they said it will be done manually. Thank goodness, we now have an integrated data base that allows us in a moment's notice to understand the kinds of patterns that are occurring around the country relative to the threats that may, in fact, be happening. But I am still not satisfied that we have done all that we need to do.

One of the things that I think should happen is that we have to focus on the first responder. I would not be in this Congress were it not for the first responder community. I was a fire chief in my hometown, became the mayor, and for the past 17 years I have worked with the fire and EMS providers in every state.

I have been to all of our major disasters from the wildlands fires in California, Oregon, Wyoming and Washington State to the mid-western floods, to hurricane Andrew and Hugo, the Murrow building bombing, the World Trade Center in 1993, and the World Trade Center in 2001, interacting with first responders and people from your agency.

Let me say, as good as we are, we are not there yet. My key focus are the first responders in the 32,000 fire and EMS departments, 85 percent of whom are volunteers, who are going to be first in on the scene when an incident occurs.

We can have the best antidotes, the best detection through our hospitals, the best systems of relaying information, but if that first-in responding officer on a police car, a paramedic unit or a fire truck doesn't understand the potential of the threat they are facing, the decisions they make in the first few minutes will determine the breadth and the scope of the impact of casualties on innocent people.

We saw that in the subway in Japan when sarin gas was used a few short years ago. The first responders in Japan weren't properly prepared. They were wiped out, because they couldn't make initial basic decisions about what it was they were facing.

Now we have begun to address this. The Congress, not the administration—The Congress in 2000 accepted a proposal by a bipartisan group of Members of Congress to establish the first assistant grant program to fire and emergency response departments. That is now up to a \$750 million funding level.

We need to continue to give them the resources to buy the handheld detection units to make basic assessments when they arrive on the scene of a disaster, because if they can't determine, not to the degree of whether they have one strain of anthrax or another but they have to be able to say we've got something unusual here—You know we've got it for the military.

I chaired the Defense Research Committee for 6 years. So I worked on the funding for all these technologies, both at Fort Detrick and with our labs. We have the technology, but these portable, handheld units are not yet in the hands of the first responder community, and there is not an integrated communication network for our first responder community in the country.

So as good as our efforts are in terms of what you are doing, and I again will commend you—I think you are doing a fantastic job—we are not there yet.

I have another actual question for you before I end my statement. I would like to know what, if any, involvement you have with Dr. Alabek, or Dr. Alabekov, his real name. Now he is at George Mason University. I have met with him many times. I had him testify before my committee 3 years ago.

He offers a wealth of information. Now he was the vice chairman of the agency who developed these strains. Doesn't it make sense to bring him in? And since we give the Russians a billion a year in external assistance, my initiative has been for the past 3 years to establish an interdisciplinary dialog and process with the appropriate Soviet or Russian scientists and laboratories to assist us in reverse engineering what they built so that we can better understand the kind of antidotes that our pharmaceutical industry has

to produce. So that is a question I would ask you to deal with in the response to my comments here.

Let me just—As you all know, we don't know where the next threat is going to occur. We all saw Dark Winter, the war game that was held in June of 2001 where the deliberate outbreak of smallpox in 3 States within 2 weeks caused 2 million people to be affected with that disease.

We all know that is the kind of potential. But again, I get back to, and I am going to continue to focus on this in every hearing where I am involved from the Office of Homeland Security, it is the first responder. It is not the Marine Corps CBR team. It is not the Army and Air National Guard. It is not FEMA bureaucrats. It is not the State health care net, although they are all important. The first responder has got to make critical decisions in the first few minutes about the extent of what the threat is.

They are not today prepared, and so while this legislation—and I commend you for it—moves us in a good direction in terms of getting the pharmaceutical industry involved, from the standpoint of the threat of bio and chemical challenges we have to do better.

Let me just say, in the end this is what I fear. I would like to do a demonstration, Mr. Chairman. We saw the sarin gas attack in a subway in Japan. This is my concern for the 1.2 million fire and EMS providers in America.

They take off a covering mechanism for the outlet, and they hit a button, and there you have a chemical or biological agent being dispersed. If this were placed in a subway, the suction of the subway trains going—this is water, so don't worry. The suction of the subway trains would carry this agent through the entire complex, such as in DC.

The Office of Technology Assessment did a study in 1993, and based on their calculations the amount of material inside of a suitcase could kill between 45,000 and 135,000 people. The first ones affected are the first responders.

So I applaud you for your work. We've got to do a lot more, and I ask your help in making sure that we don't forget those men and women who are out there every day responding to every disaster. Thank you.

Secretary THOMPSON. Let me just thank you for your passion, and I can't disagree with anything you have said, Congressman Weldon. Let me just try and quickly expand on a few things you said.

We have had Dr. Alabek in my office on different occasions. It is quite revealing. He is very innovative. He is very knowledgeable, especially on anthrax. I've had him in during the anthrax thing and had him in since then, and some people in my department meet with him. I don't know how regularly. I could find that out for you. I haven't met with him recently, but I know that he is available, and we have been, and Dr. Fauci meets with him, as I understand it, on a regular basis as well.

We have—I will never be satisfied, and I am sure you will not be as well. We have made tremendous progress. We've got a long ways to go, but I don't think we will ever be able to say, you know, we are fully prepared, because every one of these bioterrorist agents can be genetically modified.

There's going to be different ways to aerosol or disperse these particular things. As you have indicated, a very effective way was the suitcase model, but there's going to be more technologically advanced ways to do that in the future. So we are always going to have to do it.

In regards to first responders, they have got to be included. They are an integral part. They are the first responders. That's why their name is given to them. They are the first on the scene, and we are putting out tremendous amounts of dollars in order for the local State health systems to work in concert with the first responders to develop a more effective system.

We put out \$1.1 billion from our department last year. We are going to put out \$1.5 billion this year. Most of it goes to education and communications and also purchase of equipment, not only for first responders but mainly for health care workers. But we are doing a lot of things in concert with the Department of Homeland Security.

We've got to do more, but I do want to tell you that we have made tremendous progress in the past, and we are going to continue to do so. I would ask, like you, to come over and see our command center and see how far we have progressed. I think once you go through it, you will say that I didn't expect this, and I am very impressed.

Mr. SHADEGG. The Chair thanks the gentleman for his passion as well. I would point out that his time expired before he finished talking. So the Chair would call on Ms. Lowey for 8 minutes.

Ms. LOWEY. Thank you, Mr. Chairman. Secretary Thompson, Dr. Fauci, I want to welcome you and tell you how fortunate I personally feel to have two outstanding public servants head up this project, and I want to express my gratitude.

I promised my good colleague, Lois Capps, 1 minute at the end. So I am going to ask these two questions, and you will respond as best you can in the time, and then I hope we can continue the discussions.

First of all, I believe it was Secretary Thompson who said, "We are going to ask the NIH to push the research, then establish the market." There won't be many companies standing in line to do this. I find this really upsetting, and especially that the large pharmaceutical companies won't have any interest, because there won't be enough profit.

It seems to me that we may want to look into other ways to manufacture the product similar to the way the Department of Defense does. So that is the first question, because it seems unacceptable that the large companies that really can handle this won't be interested in it, and we have to dig around for some smaller companies who may not have the experience and, as you said, don't have the experience to produce this kind of product in the large quantities we need.

Second, I would like to present a specific case and follow up on my colleague Jane Harman's comments, because this is in the future. We are planning for the future. We have a problem right now, and I appreciate several of my colleagues, my colleague Mr. Weldon and others' comments.

I am aware of a company in Connecticut that has developed a drug called Prussian Blue. The drug would remove radioisotopes in a human body that has been exposed to nuclear contamination. The drug would help protect the public from a radiologic release from a dirty bomb or nuclear power plant.

The FDA has already determined that Prussian Blue provides safe or effective treatment for patients with known or suspected internal concentrations of radioactive thallium, nonradioactive thallium or radioactive cesium, but they have not approved any company's proposals to mass produce the drug due to interagency bureaucratic delays.

A potential manufacturer of Prussian Blue has had direct conversations with the Department of Energy which asked that the company expedite production of the drug. However, now the drug Prussian Blue sits, of no use to anyone, because the FDA hasn't gotten the message from the Department of Energy that this drug is critically important.

I present this to you, because it was brought to my attention. I would be interested to know how can you guarantee the American people that Project Bioshield won't experience these same frustrating gaps in coordination and communication?

I happen to have Indian Point Power Plant in my district. Many of us have nuclear power plants in our districts. All they are offering to us is potassium iodide, which affects the thyroid, but we all know and we won't go into—Dr. Fauci would have to do it—a scientific explanation if, God forbid, any kind of an incident occurs. It goes right to your bones, and you need more than the potassium iodide protecting the thyroid.

So my question is: Right now, even though we have this great proposal before us, how do we really deal with the immediate threats and move the process? FDA has probably one of the most respected processes in place. How do we make it more efficient, expedite the process so we can get some progress now? Thank you.

Secretary THOMPSON. Thank you very much, Congresswoman Lowey. I am going to allow or have Dr. Fauci answer the second part of the question. I just would like to say of the first part, I didn't say the pharmaceutical companies were not interested. I just said that there is not a market and, therefore—

Ms. LOWEY. Because there is not enough profit.

Secretary THOMPSON. Well, there is not a market. There is nobody to purchase it. So there is no reason to—

Ms. LOWEY. You are going to purchase it.

Secretary THOMPSON. Well, if we get Bioshield, we will. So I'm not saying that they will not be interested. I hope that they will be. I hope that a lot of companies will become very interested if we establish Bioshield. That is one of the reasons for us establishing Bioshield, is not only to push the research but to create the market so we do have individuals that want to come in and do things innovatively, pharmaceutical companies, biological companies, whatever the case may be, large and small.

In regard to the FDA thing, I will look into it and push it along very quickly, but I would like to have Tony—

Ms. LOWEY. Thank you.

Mr. FAUCI. I can't speak to that specific issue that you mentioned, Ms. Lowey, but you know the part of Bioshield, the third part that is the emergency use. If in fact there was the need to get something out rapidly on the emergency use authorization and it was deemed something that was safe and effective with the appropriate risk, etcetera, etcetera, and no other alternatives, you would in fact be able to get that out through the Bioshield emergency use mechanism.

That is part of the answer. The issue of speeding things along with the FDA before an attack, I think, is something that you will see the FDA—and Mark McClelland is very aware of the need of expediting issues within the framework of making sure we protect the American public from safety issues vis a vis not putting something out there that would not be safe.

So it is the balance that the FDA continually deals with, but they are very aware of the need of expediting the issues that you brought up.

Ms. LOWEY. Dr. Fauci, since I have 1 minute left, could you address the first question. NIH in concert, you said, with universities is doing spectacular research, and Secretary Thompson and yourself have concerns about the manufacturer, because people aren't interested. Couldn't we operate on a procedure similar to DoD where we might be able to produce this, because it is in the public interest, and we can't worry about tremendous profits that have to be made out there.

Mr. FAUCI. Yes, Ms. Lowey, not to comment in any way negative or whatever on the DoD process, which in many respects has worked for them, the companies, the big PhRMA as well as the biotech companies, are so good, they are so unparalleled in their capability that I personally feel as a scientist that we must embrace them in the process. They will do it quicker and better than anyone in the world.

Ms. LOWEY. Well, let me conclude and turn my time over to Lois Capps.

Secretary THOMPSON. Congresswoman Lowey, I would just was told by my lawyer behind us that we are meeting this afternoon in regards to purchasing some Prussian Blue for the stockpile. So you asked the question. That is how fast we deliver at the Department of Health and Human Services.

Ms. LOWEY. Well, I know you are efficient, and I appreciate your attention to this. Thank you. My colleague, my 1 minute remainder.

Ms. CAPPS. Oh, I really appreciate my colleague yielding me time, Mr. Secretary. There is one aspect of the Bioshield effort that is being implemented by the administration, in addition to all of our military receiving smallpox immunizations, about a half a million of our first responders have been asked to voluntarily become immunized as well to create that shield. And yet, whereas on page 19 of the administration's bill—we have discussed this—there is a permanent indefinite funding mechanism put in place, in its essence the first responders—many of these are nurses—are being asked to voluntarily risk themselves, because there is a risk associated for a small number of them, with not anywhere near the same guarantees of protection.

In the administration's proposal and also the bill that is right now before us in this committee and on the floor of the—actually, not in this committee. It has been proposed for the House, there is no guaranty of compensation that would satisfy and give first responders the confidence to step up and take this vaccination.

Don't you believe, and why is it—Don't you believe that these first responders need the same kind of protection, and why is there this disparity between the administration's bill for the Bioshield and the actual implementation of this aspect for our first responders?

Secretary THOMPSON. I don't think—

Ms. CAPPs. No mandatory spending has been associated at all with the first responders.

Secretary THOMPSON. You are talking about the mandatory. First, let me tell you. Mandatory is because it is going to be long lasting. We have to be able to create the market, Congresswoman Capps, in order to have a company go into this business and, once the research is done, that is the pull to get them to manufacturer it.

In regards to the smallpox vaccination compensation fund, we know that this is a group of individuals, and we have a discretionary amount. We know that this could be appropriated on an annual basis, if we ran out. Congress could come back and appropriate it.

It is right now, and it is immediate, and that is why we thought the discretion was a much better way to go.

Mr. SHADEGG. The time of the gentle lady, indeed the time of both gentle ladies, has expired. The Chair would call on Mr. Burr, and in doing so would remind all members of the panel that the Secretary has a firm deadline of 11:45 by which he has to depart the committee.

Mr. BURR. I thank the Chair. I welcome the Secretary and Dr. Fauci. I have three questions. I will try to buzz through them very quickly.

The first is: I would take for granted from the answers that I have heard that, Dr. Fauci, you envision that a majority of the research dollars would be extramural. Is that correct?

Mr. FAUCI. Correct.

Mr. BURR. Given that we would enter into some type of binding contractual agreement with companies, who would, in your vision, hold the patent? Would it be a shared patent or would it be, in fact, the company that we contracted with?

Mr. FAUCI. It would really vary according to the situation. For example, one example that I gave just a moment ago of a company saying we have this, we want to proceed but we need some guaranty you will buy it—That is a no-brainer. They have the patent.

In a situation when we ask for applications to come in on a product that no one is working on, that is negotiated back and forth the way it general does in collaborative relationships.

Mr. BURR. Secretary Thompson made a very valid point earlier. He said today there is no market for it, and I think we all understand the need to create the market. Anthrax is a threat here in the United States today, and next year it may be a threat throughout Europe.

When all of a sudden there is a market for that product that extends outside of the purchase agreement with the U.S. Government, do you envision that contractually there is any way for us to receive any proceeds off of the additional sales of that product through co-ownership of the patent or some reduction based upon markets that are created in the future for those companies?

Secretary THOMPSON. Congressman Burr, it certainly is possible. I mean there is no reason why we couldn't. We certainly would have an exclusive license, and after the product is developed and we put the money in for the contract, we would have an exclusive license. I don't know if we would hold the patent. We probably would not.

Mr. BURR. Well, certainly, today with NIH research there are some that criticize the fact that we spend a tremendous amount of money and a private sector company then has the patents and makes the proceeds, and I think it is important that we at least look at it, that—

Secretary THOMPSON. I think we should. I'm a big believer in that, and I certainly want to work with you in that regard. I think it is a good suggestion that we could take a hard look at.

Mr. BURR. Right. As we look at the contract itself, is it safe to say that it is impossible—Before we have even found the company that does the research, that comes up with potentially the vaccine, it is impossible for us to determine what the cost would be of the vaccine for us to purchase?

Secretary THOMPSON. I think it would be difficult, if not impossible, because—

Mr. BURR. Given that you went through that process and we got to the end, how does one then determine what the correct purchase price of that vaccine would be?

Secretary THOMPSON. It is negotiated between the Department and our procurement agents and the company, just like we negotiated the contract with Acambis-Baxter2000 on smallpox, the same way we negotiated the contract on Cipro, the same way we negotiated the contract with Aventis Pasteur to purchase their stockpile of smallpox vaccines.

Mr. BURR. But this is slightly different from the fact that we have financed their research. We probably have not paid for the machinery to manufacture, but we have paid for a number of the steps. In the traditional pharmaceutical market, one would take the research and development costs and try to recover that over the patent life of the product that was left after a very lengthy period.

Secretary THOMPSON. I sincerely think that we should try and do the same thing, as the government is to be able to get our research and development, what we have done to go into the product in order to keep the price down for the American public, because we are paying for it. But that is going to be all negotiated out.

Mr. BURR. I appreciate the fact that it is going to be part of that negotiating process, that we do have an investment in it.

Secretary THOMPSON. Well, as long as I am there, as you probably know, the contracts that I personally have negotiated, they have been very tough, and they will continue to be as long as I am Secretary.

Mr. BURR. I thank you for that commitment.

Mr. WAXMAN. Would the gentleman yield to me on this point, because it is an interesting point you have raised.

Mr. BURR. I would be happy to yield.

Mr. WAXMAN. Mr. Secretary, Congressman Burr raises an interesting point. We see this all the time. The government invests public funds in basic biomedical research. Drug companies take advantage of that, then develop a product for which they get a patent, and then have a monopoly price that they charge the public for their product.

Now many of us have felt that the government ought to be able to get some recoupment, if in no other way, by requiring lower prices when the government buys that drug. I gather what you said to Mr. Burr is that you think, if we are going to help subsidize the development of these counterterrorist measures, whether they be vaccines or otherwise, you think the government ought to get a break on the price we pay for it, if we are subsidizing the development.

Secretary THOMPSON. Yes, with the full extents of disclosure of you got to get the company to do it. I mean, you got to realize, Congressman Waxman, that there is no market out there. We are the end customer. We are the only customer that that company has. So that's all got to go into the negotiations, but we got to make sure the company is willing to manufacture it as well.

So that is all part of the negotiations that are going to take place, Congressman.

Mr. WAXMAN. If the gentleman from North Carolina would permit, I would like to ask you this question. Ordinarily, when we go out and ask for—there is a procurement issue, we go out and get an appropriation to back it up. That is certainly the case when we ask development of even drugs by the Department of Defense.

You want, however, in this bill to have a mandatory spending, an entitlement for the companies to pay for their—subsidizing their efforts to develop these products. I am curious to know why the distinction here where we have mandatory spending, first of all, and second of all, I find it hard to understand the contrast, this issue with what Ms. Capps asked you.

If we are going to have mandatory spending for the drug companies to develop vaccines, why wouldn't we have mandatory spending to make sure we compensate the first responders, the nurses, the firemen and women, the police department, if we are asking them to take the smallpox vaccine? Why wouldn't we want to treat them the same?

Secretary THOMPSON. It's two different concepts, Congressman Waxman. First off, you are going to have—You don't have a market for this particular vaccine except for the Federal Government. You are going to have the push by the NIH, putting the dollars in to getting the research done, more than likely extramural and some university. Then once the research is done, you are going to have to get a company that is going to do it.

A company, more than likely, is going to have to put in a couple hundred million dollars in order to build a new plant or a new procedure in order to produce the vaccine. Could I finish?

Mr. WAXMAN. See, I'm not arguing with you on that point. I understand that point. But if we are having mandatory spending to

do that, why not have mandatory spending to help a nurse who may be permanently disabled, to assure her that she can be made whole.

Secretary THOMPSON. I'm trying to explain it, Congressman Waxman. Because it is going to probably take 5 years, 3 or 4 or 5 years to get that product to the end result in which we would pay it. The company is not going to spend the \$200-\$300 million for the plant or the modernization of the line while waiting for us to—waiting for you and the rest of the Members of Congress to appropriate the money. They won't do it. They want to make sure that at the end of that 3 or 4 or 5 years there is going to be money available. That is why it is mandatory.

In regards to the smallpox, it is right now. We know that we have to appropriate the money, and that is discretionary with the Congress as to how much they are going to appropriate, but it is immediate. That is what we are asking for in the smallpox compensation, is to appropriate the money so that we can compensate a nurse or a first responder that has an adverse impact.

It is not 5 years. It is immediate. That is the—

Mr. WAXMAN. Well, is a nurse going to take the risk that they may not—

Mr. BURR. Recouping my time that has already expired, I would yield back to the Chair.

Mr. SHADEGG. The gentleman's time has expired, and indeed I want to thank the Secretary and Dr. Fauci. We made a commitment to get you out of here at quarter of, and that was per your schedule. You have been very generous with your time.

For any members of the committee who didn't get a chance to ask questions, I would encourage you to submit written questions, which I am certain will be responded to. With that, we will excuse this panel and invite the next panel to take their seats, and I will turn the Chair back over to Mr. Bilirakis.

Secretary THOMPSON. Thank you very much, all of you.

Mr. SHADEGG. Thank you.

Mr. BILIRAKIS. Our next panel is Dr. James Baker, Jr., Ruth Dow Doan Professor, Director of the Center for Biological Nanotechnology from Ann Arbor, Michigan, I assume associated with the University of Michigan; Dr. J. Leighton Read, General Partner of Biotechnology Industry Organization; Dr. Michael Friedman, Chief Medical Officer for Biomedical Preparedness with PhRMA; and Dr. Gary Noble, Vice President of Medical and Public Affairs, Johnson & Johnson, on behalf of AdvaMed.

Gentlemen, your written statement is a part of the record. We would hope that you would supplement it and complement it orally. We will set the clock at 5 minutes and do the best we can. Dr. Baker, I understand that there has been a family emergency. You are awfully courageous to hang on here. We will start with you, sir. Please present your opening statement.

STATEMENTS OF JAMES BAKER, JR., RUTH DOW DOAN PROFESSOR, DIRECTOR, CENTER FOR BIOLOGICAL NANOTECHNOLOGY; J. LEIGHTON READ, BIOTECHNOLOGY INDUSTRY ORGANIZATION; MICHAEL A. FRIEDMAN, CHIEF MEDICAL OFFICER FOR BIOMEDICAL PREPAREDNESS, PhRMA; AND GARY NOBLE, JOHNSON & JOHNSON

Mr. BAKER. Thank you. I am Dr. James Baker. I am a 14-year veteran of military medicine, much of that spent at Walter Reed. So I was happy to hear those kind words about it. I have also served as a reviewer of the ChemBio Terror in the DoD and as a reviewer at NIH of research that is conducted there. I have chaired several panels on bioterrorism work. So I have a broad background in this. I am also, besides being an academic, the CSO of a company that is commercializing a new non-antibiotic therapy for bioterrorism. So that gives you my background.

My presence here today is to reinforce the fact that Bioshield is going to have a number of difficulties. Many of them are technical, and that is because the concept of a bio-threat attack as an emerging infectious disease is not quite correct, I don't believe.

I think that the dose that people receive and the way that an agent is disseminated will be very different in these, and the countermeasures would have to be very different. To give an example, you know, in the military, if you are using the smallpox vaccine, it is somewhat acceptable, given the unique population. On the other hand, in the civilian population it is not, and the dissemination would be significantly different there.

So that the countermeasures that would have to be developed are inherently different. In addition, I believe that the financial issues related to return and market are much more severe than have been presented so far. I don't believe that even a government market would induce a manufacturer who has high value products and high profit margins from other applications into this field.

I believe that the work that has already been done on many of the issues related to bioterrorism and many of the research grants have attracted not big PhRMA but, in fact, have attracted small startup companies. The reason for that is that they have one focus, and their focus is developing new products.

That can work very well in your favor, because essentially there is a process at hand right now, how new products are developed. There is research that is leveraged from universities that is transferred into companies as startups that then goes through approval process, and this can be very effective in developing new technology, and the type of technology that we need under Bioshield.

So that, to give you my own example, we are funded by DARPA in my university lab, was then transferred into a commercial entity which then, within 2 years, has entered clinical trials, and this is a non-antibiotic countermeasure for anthrax.

To be quite honest, even after 9/11 there was no commercial partner that was willing to support that work, because there is no market for that and, even if they stockpiled this, was bought for a single bioterror attack, it doesn't provide the type of revenue that would interest a company with other types of revenue streams.

Therefore, I believe that the most important way that Bioshield can enhance the country's defenses is by supporting this type of on-

going process, by leveraging the research that they are already paying for in the universities, and by enhancing tech transfer and startup endeavors for this type of work.

I think there are many examples how this will work, but I think most importantly I don't think, even with the types of incentives that are being written into Bioshield, it will prove enough of a lure to get large companies involved in this type of endeavor, even if an artificial market is created. Thank you.

[The prepared statement of James Baker, Jr. follows:]

PREPARED STATEMENT OF JAMES BAKER, JR., RUTH DOW DOAN PROFESSOR, CENTER FOR BIOLOGICAL NANOTECHNOLOGY

I am Dr. James Baker, a physician who is the Ruth Dow Doan Professor of Internal Medicine and Director of the Center for Biologic Nanotechnology at the University of Michigan. I am Director of Research at our institution's Bioterrorism Initiative, and Division Chief of Allergy and Clinical Immunology in the Medical School. I am a 14-year veteran of service in the U.S. Army, 12 of it on active duty, including service during Desert Storm. I have participated in and chaired committees in NIAID reviewing research into defense against biologic weapons. With support from the Defense Advance Research Projects Agency, the National Institutes of Health and NASA, my center is applying these technologies to a number of problems in biology including infectious disease therapy and microbial decontamination. I am also the CSO of two startup companies, one of which, NanoBio Corporation, is dedicated to commercializing new technologies for antimicrobial applications and decontamination. I have extensively studied the problems involved in preventing illness as a result of bio-terrorism or bio-warfare, and I am pleased to have been invited to testify before the committee this morning.

The Purpose of Project Bioshield

Project Bioshield aims to rapidly transfer technology into products that can be used to protect individuals against biologic and chemical agents used as weapons of terrorism or mass destruction. The emphasis is on rapid introduction of new countermeasures into actual use, as many technologies currently under development need to be transitioned through regulatory approval or commercial development cycles. Unfortunately, Project Bioshield faces many challenges in attaining this goal. Some of these challenges are technical. The technologies that are currently available for commercialization are not adequate to meet the needs of our population. An excellent example is the current smallpox vaccine which is being produced in larger quantities but has medical issues that make it unacceptable for use by the current U.S. population. While new smallpox vaccines are in development, the time lag for approval of these is considerable and beyond the timeframe desired for Project Bioshield.

Other problems for Project Bioshield involve economic issues. Producing technologies solely for bioterrorism prevention is not economically viable for most companies. Since most products specifically targeted for defense against bioterrorism will hopefully never be used, small sales of these products would have to support massive development costs, even when aided by the government. Also, it is unlikely that established manufacturers will bid to produce products only for these applications since there would be no consistent, ongoing markets available to sustain product development and marketing costs. Finally, the cost of product liability may be an inherent issue in this process. Unlike products developed for the military, products directed towards civilian applications expose manufacturers to liability claims. A product, be it a detector, vaccine or therapeutic, will not be infallible and the risk of failure during a bioterrorism event would create liability issues great enough to prevent any established company from entering this market. This is apparent in many of the bioterror initiatives the government has already launched.

The result of these many problems requires that most work supported by Project Bioshield will involve new technology developed by start-up companies who are willing to support the high-risk, high-reward nature of bioterrorism applications. In addition, this approach will also ensure that the American people get the best available technology, and leverage the investment in government-sponsored research from NIH, NSF and the EPA.

The Nation's Best, Largest Technology Incubator

The nation's best and largest technology incubators are its' research universities. Most of the breakthrough technologies that have been incorporated into medical research and therapeutics have come from the nation's research university laboratories. These research advances cover the gamut of Project Bioshield needs from medical counter-measures, such as vaccines and therapeutics, through issues related to the psychological and economical impact of bioterrorism. The nation's universities produce new technologies very efficiently, given that they have a pre-installed technical base. The universities are also highly effective in technology transfer, being the source of much of the technology used by the nation's start-up biotechnology and pharmaceutical research companies. These start-up companies are most likely to respond to Project Bioshield given the fact they are willing to accept the risks involved in developing new technology for bioterrorism. This system is remarkably efficient; yielding new companies and new technologies rapidly and often without support from established companies. The focus also is on technology improvement to do a better job of protecting our citizens, rather than re-packaging current technologies.

My Personal Experiences Emblematic Of This System

As a physician scientist I received funding from DARPA to develop new counter-measures for bioterrorism. This research quickly resulted in technology that was commercialized. NanoBio, a start-up company where I am Chief Scientific Officer, began work in March of 2001 and quickly responded to a request for decontamination materials during October 2001. Given our technology's unique application to skin decontamination, we have now moved towards FDA approval to use our material to decontaminate human beings and are initiating Phase I clinical trials this spring. This was accomplished despite the regulatory approach for bioterrorism approval being defined only 6 months ago. Thus, the head start given to our technology by university research and development was leveraged into a commercial product that will enter clinical trials less than two years after the company was created! It is this type of success that could be duplicated many times with academic support through Project Bioshield.

Proposal for Inclusion of Research University Components in Bioshield

I would strongly urge you to include research university components in the Bioshield bill in order to support the transition and commercialization of university research. This will support and leverage funding to develop new technologies these universities have received from the NIH, NSF and EPA. It will also ensure that the newest and most effective forms of protection are made available to our population. Finally, given the economic and liability issues involved, it is likely that only start-up and small companies would accept the high-risk, high-reward endeavors entailed in Bioshield. By leveraging the government's investment in university research, the likelihood that these companies will be successful is increased for the betterment of all.

Mr. BILIRAKIS. Thank you, Dr. Baker.

Dr. Read.

STATEMENT OF J. LEIGHTON READ

Mr. READ. Thank you, Mr. Chairman and members. I appreciate the chance to comment here today, and I just have to say how impressed I am with the sophistication of the comments of yourself and the members on this very complicated important issue.

My comments are based on my experience as a physician and as an entrepreneur who started and built a number of successful biotech companies, and now as a venture capitalist investing in entrepreneurs working on astonishing technology in biotech and information technology. I am honored to represent the Biotechnology Industry Association today and its 1100 members, which include companies, research institutions, State associations in all 50 States.

Bioshield is a huge step forward, and it deserves the urgent consideration of this committee. Some of its important features that are extremely welcome include this essential delineation of respon-

sibilities between the Secretaries of Health and Human Services and Homeland Security.

Some of the streamlining of the ability of NIAID to sponsor both intramural and extramural research, the emergency powers for the Secretary are to help accelerate the ability to make good decisions under what will then be very difficult circumstances and, of course, the serious effort to deal with market creation and the role of the private sector.

I have adapted my remarks in light of some of these wonderfully incisive questions today. What is the role of the private sector? What is the case for the private sector's engagement in creating these countermeasures?

One, our system is based on this kind of pluralism. Most of—The second thing that I think is raised very heavily here is the track record. It is true that most of the vaccines and antimicrobial agents produced and introduced into actual clinical use in the last 30 years—you can trace the roots to a very important NIH and often NIAID contribution to the basic science and sometimes far beyond that, but in every single case of a product that is available to American doctors and their patients today, there has been a gigantic investment by the private sector.

The third reason is that there are vast resources in the private sector. It would be wildly failing to take advantage of these resources if we were not to recognize that there are very specialized skills and simply large numbers of capable people and experience in the biotechnology and pharmaceutical sector.

So the question—many of the points have already been made today—how do we get the private sector fully, effectively, appropriately engaged and have the appropriate safeguards? I do think this idea of push and pull mechanisms is important as a way to think about this. The way I would use the terms, a push mechanism is something that lowers the cost of getting the job done, of developing and—of discovering and developing countermeasures, and so support for R&D is a good example of a push mechanism, and there is a place for that.

I would describe pull mechanisms as mechanisms which increase the reward rather than lowering the cost. So increase the reward for success. It is really important that these pull mechanisms not be degraded by then taking away some of that reward for success. I will have a couple of examples.

Push deals with process. If we fund push mechanisms generously, what we tend to get is more process. We create a dependency, both in all of our institutions, public and private sector, when we fund that. We create a group that exists and will be productive in that mode. If we focus some or a large portion of our resources on pull mechanisms, what we are rewarding is the end result we care about.

One of the reasons that really clear examples and models for pull mechanisms are challenging for countermeasures in this setting is that we are still in the early days of delineating our threat list. We have this list of agents, but we know that the creativity of our opponents is tremendous. The tools are available. They are already disseminated. The preparation is already there.

So we need to have a constructive, flexible, incisive and centralized point of setting these priorities so that we can then design our pull mechanisms around these targets. by the way, I think there is an important role for both vaccines and drugs and diagnostics, some of which will be very specific to known pathogens where we know that tons of these things were produced somewhere and might be in the hands of our opponents.

In other cases, we really need to create the incentives, the pull mechanisms, supplemented with push to create more broad or general purpose medicines and approaches that don't even exist today. We need to work on the priority list, and having it centralized is going to be important.

I want to say a word about a couple of things that could take away from the value of the pull mechanisms that are embodied in the current legislation.

Mr. BILIRAKIS. Can you do it in a summary, in a summarized fashion?

Mr. READ. Okay, thank you, sir. In summary, I think the 5-year limit and the penalty for success with dual use, the fact that this procurement is only limited to a setting where only the government work, means that we are penalizing the innovators for their success and, of course, it is going to be important to provide some form of protection from crippling lawsuits when that is appropriate. Thank you, Mr. Chairman.

[The prepared statement of J. Leighton Read follows:]

PREPARED STATEMENT OF J. LEIGHTON READ, GENERAL PARTNER, ALLOY VENTURES
ON BEHALF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION

Mr. Chairman and Members of the Committee, it is an honor for me to testify before you today regarding Project BioShield and its likely impact in bringing private sector talent and investment into our nation's biodefense effort. I would also like to recognize Secretary Thompson and Dr. Anthony Fauci for their testimony here today and their continued leadership on issues relating to the health of the American public. BIO applauds your immediate consideration of the proposed BioShield initiative, which is designed in part to stimulate research and development of biomedical countermeasures through collaboration with the biotechnology industry.

These comments are based on fifteen years of experience building and financing biotechnology companies in Silicon Valley. I am co-founder of Affymax, a company that transformed the way the pharmaceutical industry thinks about screening for new drugs and a co-inventor of the technology underlying the Affymetrix GeneChip™, the leading technology for acquiring, analyzing, and managing complex genetic information for use in biomedical research. I was founder and CEO of Aviron, a vaccine discovery and development company with extensive and successful experience partnering with the National Institute of Allergy and Infectious Disease. When Aviron merged with MedImmune, a fine company near here in Gaithersburg, I joined Alloy Ventures, a venture capital fund investing in entrepreneurs building early-stage companies in the life sciences and in information and communication technology. Previously, I held faculty appointments at Harvard Medical School and School of Public Health, where I practiced internal medicine and conducted research on the costs, risks and benefits of new medicines. For a number of years, I served as a member of the Executive Committee of the Biotechnology Industry Organization (BIO), who I am also representing today. BIO represents over 1,100 companies, universities, research institutions, state biotechnology associations and affiliates in all 50 states.

PROJECT BIOSHIELD IS A MAJOR STEP FORWARD

By focusing energy and resources on the creation of new biomedical countermeasures, this legislation will certainly contribute to our national preparedness. Its delineation of responsibilities among the Departments of Health and Human Serv-

ices (HHS) and the Department of Homeland Security (DHS) provides essential clarification to minimize gaps and duplication of effort. The legislation contains many provisions that will help the National Institute of Allergy and Infectious Diseases (NIAID) streamline work on its essential mission of creating new knowledge about infectious disease and countermeasures. New authorization for procurement of medical products to be used in emergencies is highly welcome because it will facilitate good decision-making under the very difficult circumstances that must be part of our planning horizon.

And—very importantly—BioShield contains provisions that recognize some of the unique challenges in producing biomedical countermeasures and the importance of engaging the private sector in this vital effort. The procurement provisions of BioShield begins to address the need for “pull” mechanisms of market creation that are essential to complement “push” mechanisms, such as sponsored R&D programs already enacted.

Our country will only be successful in placing needed countermeasures on the shelf if the Government is able to engage the enthusiastic participation of leading companies in the biotechnology and pharmaceutical industry. The conditions are not yet in place to accomplish that goal. BioShield is a step in the right direction, particularly with respect to procurement of near-term products. In the long term, in addition to BioShield, there are a range of “push” and “pull” incentive mechanisms that the Committee and the Administration should evaluate, such as those included in the proposal by Senators Lieberman and Hatch.

WE ARE AT THE BEGINNING OF A VERY LONG ROAD

I am concerned that several of the provisions in BioShield miss an important chance to address our country's long-term needs. America's role in the world positions us as a uniquely attractive and vulnerable target for asymmetrical warfare tactics embodied in today's terrorism. While public recognition of this threat may be a recent phenomenon, we can plan on facing this challenge as long as our prosperity and influence set us apart from other nations.

WE MUST CREATE A NEW BIODEFENSE INDUSTRY TO PARTNER WITH THE GOVERNMENT

The scale of the investment required is many-fold larger than implied by the current BioShield proposal. Only two, the anthrax and smallpox vaccines, of 57 diagnostics, vaccines and therapeutic products prioritized by the Defense Science Board (DSB) are available today. BIO and our member companies had met on numerous occasions with various agencies engaged in homeland security prior to the establishment of the separate department. BioShield will provide much needed centralization of these efforts, as well as a clear list of R & D priorities that can focus private sector investment if coupled with the right market signals. At the current investment levels, some new countermeasures will be available within five years, however larger investments will undoubtedly be required. Over the long-term this challenge and the necessary investment may be compared with the nuclear threat of the late 20th century.

Fortunately, we can ensure that government investments are well rewarded by basing our policies on models of successful biomedical investment. It is important to seize this opportunity because infectious diseases represent some of our greatest triumphs in discovering, preventing and treating disease. When the public and private sector biomedical research assets of the United States are focused on high priority infectious disease targets, the result has ranged from complete conquest—as in the case of polio—to medicines that significantly reduce mortality and improve quality of life. Young doctors today have never seen the childhood infections that accounted for most infant mortality 50 years ago. Even the HIV virus, which has so far eluded attempts to find an effective vaccine, can be controlled with a growing number of drugs discovered and launched in only 15 years.

Public-private partnerships are working to control infectious disease. Antibiotics, anti-virals, vaccines and other “wonder drugs” against infectious disease come to be available to patients and their doctors via a complex web of interactions among public and private sector entities. In the past 30 years, almost every important antimicrobial drug and vaccine discovery effort has benefited in some way from the research conducted under the sponsorship of the US National Institutes of Health (NIH). Through its intramural and extramural programs, the NIH is responsible for an explosion in the basic science of how infectious agents spread and cause disease and how the human body fights back. The NIH has also made substantial progress by moving discoveries out of the laboratory and into clinical trials where safety and efficacy can be evaluated. For example, results from Vaccine Trial and Evaluation Units (VTEUs) in academic institutions supported by NIAID demonstrate how suc-

cessful public-private partnerships can be. Other Federal programs at the Centers for Disease Control and Prevention (CDC) and elsewhere in HHS, as well as in the Department of Defense (DOD) and the Veterans Administration (VA), have made important contributions.

Government supported facilities for research on biothreat agents will play a critical part in the research and development efforts of both public and private contributors. It is not feasible for the private sector to build or operate all of the biocontainment facilities needed, and it is essential that countermeasure candidates developed in the private sector can be tested for pre-clinical efficacy in the public funded facilities, especially where physical control of dangerous biothreat agents must be assured.

The government plays a further vital role by setting minimum standards for product safety and efficacy via the FDA. This gate-keeping role also extends to regulation of manufacturing processes. The large extent to which regulation of manufacturing drives the cost and development time of vaccines and related products is an important consideration for biodefense procurement policy.

Finally, the government has successfully created large and enticing markets for bio-innovations by serving directly as a purchaser, via the Medicare, Medicaid and Veterans' healthcare programs, and via the regulatory and tax environment that supports our large private health insurance industry. By creating conditions for a market that is reasonably predictable and consistent over time, the government should set the stage for the private sector to optimize its use of resources to develop appropriate products. The same concepts of consistency and sustainability, while not perfect in these and other purchasing environments, will be needed for the development of countermeasures to biothreats. Particularly when you consider that the market for countermeasures cannot, by any definition, be considered a traditional market.

As important as the government's role is, it can also be said that *all* of the important drugs and vaccines for infectious disease in the US have come to be available only after substantial effort and investment by private sector companies in the pharmaceutical and biotechnology industries. Some of these programs began as early-stage discovery programs in industrial laboratories. Often, these benefited from technology licensed from our great research universities, where discoveries were typically funded by government grants. Still others were the result of technology transferred by the NIH or other agencies to a committed industrial partner under licenses and Cooperative Research and Development Agreements (CRADAs). Regardless of where industry stepped in, every successful product has required private investment ranging from tens to hundreds of millions of dollars.

THE CRADA FOR FLUMIST™

My company, Aviron, held one of the first CRADAs with NIAID beginning in 1995. This work involved a promising influenza vaccine invented at the University of Michigan in the 1960s under US Army sponsorship. This vaccine had been the subject of NIH-sponsored clinical trials in VTEUs thru the 70s and 80s. Despite the lack of a committed industrial sponsor, NIAID had built an impressive base of scientific knowledge around this flu vaccine and its novel form of administration via the nose. There were major contributions from the NIAID intramural program as well as its network of vaccine trial and evaluation units. Under our 5-year CRADA, Aviron developed a manufacturing process and supply chain and conducted Phase II and Phase III clinical trials for FDA registration of the candidate vaccine now known as FluMist™. The partnership between Aviron and NIAID was as successful as it was collegial, with each side performing its roles in bringing the vaccine forward. What neither party anticipated at the outset was the staggering cost of late-stage vaccine development and manufacturing to FDA standards. More than \$300 million has been spent over the past 8 years to bring FluMist™ to the point of final FDA evaluation. This is for a vaccine technology that had been the subject of over 20 years of NIH clinical trials!

The money to support this work was supplied by venture capital firms and public market investors in our IPO and numerous follow-on financings. The incentive for the private sector to make these huge investments is premised on the size of the market for successful innovations, which can reach many hundreds of millions of dollars in annual sales. While American companies can be counted on to respond to a crisis, efforts to attract the best people and companies to work for many years on high-risk countermeasure projects will fail if the reward structure is not aligned with the prevailing incentives in their industry.

Venture capitalists do not, as a rule, invest in companies with business models such as professional services firms or companies aiming to build a business based

on contract R&D at industry averages. We aim for our companies to produce products based on defensible intellectual property which have the kinds of margins seen in truly innovative software, pharmaceuticals, and electronic devices. Year in and year out, through the natural cycles of technology, this is a proven recipe for creating value for consumers, patients and investors. That is why I am so concerned that we are not giving full attention to the actual products we need to build in the end and the market forces that will get them finished, deployed and sustained.

EXTENDING BIOSHIELD

BioShield should be extended to cover the time frame and scale of the problem. The Secretary needs the flexibility to choose the appropriate mechanisms to develop countermeasures, sole-source or through competitive means, and mechanisms for obtaining advice as to what is likely to be most effective for different technologies. Through the use of an appropriate advisory board, which would include industry participation, with the necessary anti-trust waivers the Secretary will more likely be able to obtain state of art expertise from the private sector in addition to others.

We must signal to private sector enterprises, and the vast capital markets that are available to support them, that there will be a meaningful reward for successful new technology addressing our highest priority needs. The most important enhancement for BioShield is to create more certainty that there will be a market when the private sector innovator succeeds in creating a product with previously defined specifications. The current proposal only authorizes—and does not guarantee—that the Government will purchase. This guarantee is especially important in order to spur investment in countermeasures that are earlier in development and thus years away from commercial success. To be effective, this will require some creative new approaches to overcome industry skepticism regarding government holding to its promises. One such mechanism is a guaranteed purchase fund, as has been proposed to stimulate R&D for new malaria, tuberculosis and HIV vaccines.

The restriction on BioShield procurement to countermeasures reasonably expected to be available in 5 years is highly limiting, in light of the actual development time for new drugs and vaccines. This will be abundantly clear as soon as HHS, DHS and DOD have harmonized the various threat agent and countermeasure priority lists. If the hope is that “push” mechanisms such as government sponsored research will bring a whole generation of products far enough along so that they can be commercialized within the 5-year restriction, we are setting a policy that fails to take advantage of the private sector’s abundant willingness to take on early risk when there are clear market rewards for success. A more reasonable calculation of development time is between 7 and 15 years (indeed the products that are most difficult to develop maybe the most important ones). We thus recommend that the proposal’s limitation on “qualified countermeasures” eligible for procurement to those expected to be produced and delivered within 5 years be deleted.

Why should we take the beneficial procurement provisions of BioShield off of the table for technology having borderline civilian prospects? The surest way to shut off investment is to raise the specter that success will be punished! The no-significant-commercial-market provision will ensure that the private sector will under invest in countermeasures that are a close call because of the risk that the government will decide some future dual use is too successful. Further, this uncertainty creates a system that may exclude products with potential application as countermeasures, possibly be those closest to the market for other purposes.

PRODUCT-LIABILITY CONCERNS COULD DEFEAT OUR BEST EFFORTS TO ENGAGE THE PRIVATE SECTOR

In addition to the need to create a market for countermeasures, the Government must assure private sector partners that they will not be exposed to a risk of litigation out of proportion to the rewards for success. Companies make judgments about product liability risk all the time in the normal course of business, but biomedical countermeasures pose particular challenges. In the absence of improved market incentives for successful innovation, many will find that potential litigation weighs heavily against proceeding. Even with strengthened market incentives, the unfamiliarity of the exposure magnifies perceived risk, especially when the private sector company may have little control over how the government deploys the countermeasure.

As this committee knows, on several occasions, Congress has protected companies from liability when the public health and the national defense so required. The Price-Anderson Act—of 1957 encouraged the development of a civilian—nuclear energy industry—by limiting the liability of companies that support the nation’s nuclear weapons program as well as those who design and operate civilian nuclear

power reactors. The Swine Flu Law, enacted in 1976, brought manufacturers of that vaccine under provisions of the Federal Tort Claims Act in order to allow mass immunizations. The National Childhood Vaccine Injury Act of 1986 responded to the threat that the pertussis vaccine and other vaccines would be withdrawn from the market due to the significant costs of defending lawsuits—by providing both a no-fault compensation system and Federal standards applicable to lawsuits if no-fault claims were unsuccessful or rejected by the claimant. And, of course, last year's Homeland Security Act (P.L. 107-296) provided protections for the manufacturers of the smallpox vaccine and—government contractors who provide “qualified anti-terrorism technologies.” In addition, the BioShield proposal drafted by the Administration includes protection under the Federal Tort Claims Act for contractors who participate in personal services contracts under the new research and development program established under Section 2 of the Administration's proposal.

Legislation implementing the BioShield initiative should extend a liability protection program that is applicable to the proposal's three features: research and development activities under Section 2, the procurement program under Section 3, as well as to the products approved under the proposed “emergency use” revisions to food and drug law under Section 4.

BIO recommends extending the protections offered under Section 304 of the Homeland Security Act to biomedical countermeasures and medical products other than those used to combat smallpox. Following this approach, the Federal Tort Claims Act would clearly be extended to cover manufacturers and developers of biomedical countermeasures, as well as manufacturers of medical products granted an authorization for use in an emergency situation. By creating a system under which manufacturers are protected from enterprise threatening liability mentioned, the Government will establish a true partnership with industry that will facilitate the development and production of the most advanced tools possible to counter possible bioterrorism attacks.

AUTHORIZATION FOR EMERGENCY USE

BIO supports the concept of waiving FDA approval requirements for a product intended solely for emergency use, such as that found in Section 4 of the Administration's proposal. Our major concerns involve the lack of assurance that a company is consulted on the terms and conditions of approval. We also believe that the proposed inclusion of civil monetary penalties to the emergency use provision is much too broad, and we recommend deletion of this provision.

CONCLUSION

In sum, Mr. Chairman, the proposed BioShield initiative is an important step towards mounting an effective effort by the federal government, to spur research and development of biothreat countermeasures through public and private sector partnering with the biomedical research community and the biotechnology industry. Undoubtedly, this effort can be made much more effective through legislative language that guarantees procurement when the research and development has been successful, and provides rational protection against crippling lawsuits. Finally, it is critical to recognize that, realistically speaking, development of vaccines, therapeutics and diagnostics typically takes more than 5 years, so it is paramount that some form of guaranteed “pull” incentives are included in a final bill because of the non-traditional market that will exist for potential biothreat countermeasures.

Mr. Chairman, thank you for the opportunity to testify on this tremendously important issue. The biotechnology industry is committed to contributing to our nation's common defense and achieving the goals articulated by the President in his Project BioShield initiative. I will be pleased to respond to any questions from members of the Committee.

Mr. BILIRAKIS. Thank you very much, Dr. Read.
Dr. Friedman.

STATEMENT OF MICHAEL A. FRIEDMAN

Mr. FRIEDMAN. Thank you, Mr. Chairman and members of the subcommittees. On behalf of the Pharmaceutical Research and Manufacturers of America, I am pleased to be here today to share with you the views of the research based pharmaceutical industry on the President's Project Bioshield initiative.

Biological weapons represent an increasingly serious danger to people around the world. The dynamic complexity of the problem is demonstrated by science's difficulties in dealing with both naturally occurring infectious disease as well as intentional bioterrorist attacks.

While PhRMA companies are the process of developing more than 200 new medicines to treat or prevent various infectious diseases, reports by the National Academy of Sciences, the NIH blue ribbon panel on biodefense research, and the U.S. Defense Science Board make it clear that an even larger number of more diverse types of countermeasures must also be developed, and they must be developed promptly.

Although the basic science research required for countermeasure development is currently being supported by Federal agencies, it is widely recognized that more sponsored research is necessary. There also needs to be more flexible authority and more resources for regulatory agencies. In short, those things which will advance the development and production of the countermeasures.

PhRMA member companies have been active in moving forward on countermeasure research and development, as I have outlined in my written testimony. There are numerous examples of how we have worked with CDC, DoD, NIH, FDA and academia to support a whole range of activities, and I won't try to repeat those now. A cooperative and collaborative research and development effort which engages industry, government and academia will, however, be essential to this successful effort.

PhRMA believes that Project Bioshield is an important step toward this, and we support the three main components of the President's proposal. The President's proposal speaks primarily to the early and to the later steps in the lengthy, high risk and costly process of bringing new medicines to the market. It does not, however, speak to the time consuming and resource intensive middle part of that process which we see is largely our responsibility.

Further research into bio-threat countermeasures represents challenges beyond those ordinarily encountered in non-biodefense R&D. These include scientific, economic, and legal challenges, and let me enumerate just a couple of examples, if I may.

Some products will be distributed without the typical battery of clinical trials that are required for FDA approval. All medicines present an inherent and unavoidable risk of adverse events. As a result, manufacturers may be exposed to devastating product liability suits, and it has been pointed out here today that not only the companies but also those patients who receive it and those people who administer these treatments also may be affected by those suits. Private insurance may simply be unavailable.

The need for rapid development of countermeasures may require the sharing of scientific information and cooperation amongst many different companies, for example, the sharing of data by researchers working in different areas. Collaboration and cooperation in this research might create exposure under current anti-trust laws.

A third point is diverting resources from research and development of other medicines will affect the future availability of treatments and cures for patients with serious health conditions, especially since only a tiny percent of all the drugs that enter testing

ever demonstrate sufficient human safety and acceptable efficacy. The allocation of resources can be particularly difficult for companies with few products in the pipeline.

In order to meet the public health needs of our citizens, PhRMA looks forward to working in a transparent manner with Congress and the administration to enact measures that will provide appropriate and equitable product liability protection in this very special context, as well as narrowly tailored measures to address anti-trust constraints, where appropriate, in order to allow the needed collaboration and the consortia with industry.

Cooperation and strong commitment from all parties will be necessary in the years to come as our Nation seeks to protect itself against the real threats of bio-warfare and bio-terrorism. America's pharmaceutical companies look forward to doing our part. I thank you for this opportunity to address you.

[The prepared statement of Michael A. Friedman follows:]

PREPARED STATEMENT OF MICHAEL A. FRIEDMAN ON BEHALF OF THE
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to share with this Subcommittee the views of the research-based pharmaceutical industry on the President's Project Bioshield Initiative. PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which invested an estimated \$32 billion in 2002 in developing new medicines to help and heal patients.

PhRMA member companies join others who are convinced that biological weapons present a serious and increasing danger to people around the world. The pharmaceutical industry is dedicated to the development of innovative therapies and vaccines to counter unmet medical needs. Because a substantial proportion of the unmet medical need in the United States and worldwide is both directly and indirectly related to infectious diseases, we understand only too well the seriousness of the threat of biological agents if used as weapons of war.

The complexity of the problem of biological weapons is best demonstrated by humanity's ongoing difficulty in dealing with infectious agents as the cause of natural disease, let alone their potential use for intentional concentrated exposure of selected populations. The threat represented by infectious diseases—such as HIV, malaria, and tuberculosis—is real and all too well demonstrated by the deaths of over 5 million people annually from these three diseases alone. All together, infectious diseases claim more than 100,000 American lives each year, and cost more than \$30 billion annually in direct treatment expenses alone. At last count, PhRMA member companies were developing 256 new medicines to treat or prevent infectious diseases; medicines which include brand new classes of antibiotics, new vaccines (including edible vaccines), antifungals, antivirals, and immune enhancers.

Reports from the National Academy of Sciences, the NIH Blue Ribbon Panel for Biodefense Research, and the US Defense Science Board, make clear that a large number of countermeasures to biothreats must also be developed. These countermeasures include vaccines, therapeutics, and diagnostics. The basic science research required for countermeasure development has already been stimulated by funds appropriated to various federal agencies including the Department of Health and Human Services and the Department of Defense. However it is widely recognized that more is needed with respect to funding of basic research, to increased authority for funding and regulatory agencies, and to the advanced development and production of the countermeasures.

A cooperative and collaborative research and development effort, which engages industry, government, and academia, will be essential to that effort. Existing medicines are not sufficient to combat the biological weapons already developed. Research and development into new medicines is a lengthy, risky, and expensive endeavor. Research into biothreat countermeasures involves several challenges above and beyond those encountered in non-biodefense R&D. For example, biodefense R&D requires working with dangerous pathogens in highly specialized facilities, and developing countermeasures without a full picture of the risk of disease (because we cannot see into the mind of the terrorist) or the benefit of the treatment (because

there are often no patients with the disease, which prevents clinical testing for efficacy).

PhRMA and its member companies are already working closely with federal agencies and academia to move forward with this research. For example, PhRMA is working with CDC, DoD, NIH, FDA, and academia to support in vitro studies of five pathogens (*B. anthracis*, *Y. pestis*, *Brucella* spp., *F. tularensis*, and *Burkholderia* spp.) for testing of existing antibiotics. Several companies are working with the National Institute of Allergy and Infectious Diseases (NIAID), the Department of Defense, and the FDA to test existing antibiotics against plague, and PhRMA will co-sponsor a workshop with interested parties to determine how best to expand labeling of other existing antibiotics that may be effective against the top biothreat agents. PhRMA committees continue to work with FDA to clarify and improve existing regulations that pertain to biothreat countermeasure research, such as Part 600 (the Spore Formers Rule, which imposes requirements on use of facilities or equipment that have been used with spore forming organisms), and the Animal Rule (which allows efficacy testing in animals where testing in humans would be impossible or unethical). We have prepared educational materials for the public on anthrax, smallpox, and vaccinia, and we are working on materials addressing tularemia and plague. Dr. Gail Cassell, PhRMA's Chief Scientific Officer for Emergency Preparedness and Vice President, Scientific Affairs at Eli Lilly & Co., sits on Secretary Thompson's Advisory Council on Public Health Preparedness. A Biosurveillance workgroup involving PhRMA and other private sector companies (TIGR, IBM, and Roche Diagnostics) along with federal agencies (CDC, DoD, NIH) and the World Health Organization to establish a global infectious disease electronic surveillance network.

PhRMA believes that Project Bioshield, announced by President Bush in his 2003 State of the Union address, is an important step forward in the effort to ensure the development of modern, effective medicines and vaccines against biothreats and to ensure that these medicines are made available in a timely and efficient manner. PhRMA generally supports the three main components of the President's proposal: first, the creation of a permanent indefinite funding authority to spur the development of medicines and vaccines by the private sector; second, new authority for NIH to speed promising R&D through streamlined hiring and procurement mechanisms and increased flexibility to award contracts and grants; and third, new FDA emergency use authorization for promising treatments still under development.

At the same time, however, it is necessary to recognize scientific, legal, and economic impediments to the research and development of biodefense products. Manufacturers may be exposed to devastating product-liability suits. Some of these would arise out of adverse events that are unavoidable given the nature of the products, and some could arise simply because the products were made available without the usual battery of clinical trials required for FDA-approved products. Private insurance can be unavailable or prohibitively expensive for such products. The decision to divert resources from the research and development of medicines for serious illnesses like heart disease can be financially risky, especially when a countermeasure may never be purchased or used, and especially for companies with few products in the pipeline. (Diverting resources from research and development of these other medicines will also affect the future availability of treatments and cures for patients with other serious health conditions—especially since less than ten percent of all drugs that enter testing ever demonstrate sufficient safety and acceptable efficacy.) The need for urgent development of medicines may require the sharing of information and cooperation among companies, which can raise antitrust concerns. The scientific challenges inherent in research into bioterrorism countermeasures, for example, may require cooperation and collaboration among scientific experts in different companies. (For example, there have been only two new classes of antibiotics developed in the last 40 years.) PhRMA looks forward to working closely with Congress and the Administration to enact measures that will provide appropriate product liability protection and address these antitrust constraints.

Cooperation and strong commitment from all parties will be necessary in the months and years to come, as our nation seeks to protect itself against the terrible threats of biowarfare and bioterrorism. America's pharmaceutical companies look forward to doing our part.

We thank you for your time and look forward to answering your questions.

March 25, 2003

THE NEED FOR AN ANTITRUST EXEMPTION TO ENABLE PHARMACEUTICAL COMPANIES TO RESPOND TO GOVERNMENT REQUESTS FOR HELP TO COMBAT BIOTERRORISM

In the aftermath of the attacks of September 11 and the use of anthrax as a terror weapon, the pharmaceutical industry has been asked by various government officials, particularly the Secretary of Health and Human Services, to help reduce our vulnerability to the threat of bioterrorism. The antitrust laws present a significant restraint on the pharmaceutical industry's ability to provide assistance. Accordingly, a limited antitrust exemption is warranted for joint efforts undertaken under government auspices to develop bioterrorism countermeasures. Such an exemption, for which there are several historical precedents, would further the government's program to ensure that the country is prepared to respond to an act of bioterrorism and would not undermine the important protections imposed by the antitrust laws.

FIGHTING BIOTERRORISM WILL REQUIRE A COORDINATED INDUSTRY RESPONSE

As the country learns more about the potential threats posed by bioterrorism, the research and production expertise of the nation's pharmaceutical industry could be called into service in a variety of ways. Likely requests for assistance include:

- An exchange of information by pharmaceutical companies on individual vaccine manufacturing capacity to develop an industry aggregate assessment of capacity.
- An HHS sponsored agreement that one group of pharmaceutical companies devote research and manufacturing capacity to one area, such as a smallpox vaccine, and that another group of companies focus on another area, such as anthrax treatments.
- An HHS request that the companies agree that, in the event of a bioterrorism event, they will dedicate their research and manufacturing resources on an emergency basis in a manner directed by HHS.
- A procedure by which pharmaceutical companies share research results and manufacturing best practices to allow for the rapid production of needed bioterrorism countermeasures.

While each of these steps would increase the nation's ability to respond to the bioterrorism threat, individual pharmaceutical companies may be unable to participate in these types of joint efforts without some assurance that its conduct will not be challenged as a violation of the antitrust laws.

THE ANTITRUST LAWS BAR JOINT ACTION BY COMPETITORS REGARDLESS OF SOCIAL NEED

Section 1 of the Sherman Act—the provision of the antitrust laws most pertinent to this issue—prohibits agreements between competitors that unreasonably restrain trade. The pharmaceutical companies would be hampered in their ability to defend joint responses to government requests notwithstanding the existence of an overwhelming public health benefit for several reasons:

- Some agreements, including agreements among competitors to allocate resources across a range of projects, can be *per se* illegal notwithstanding compelling justifications.
- Even under the rule of reason, the Supreme Court has held that agreements must be justified under the Sherman Act as promoting competition and may not be justified by public policy considerations, such as safety and health.
- Absent specific statutory authorization, government officials lack authority to grant immunity from antitrust challenge.

Furthermore, antitrust claims frequently are expensive to defend and inherently difficult to predict in their outcome. As a matter of prudent business practice, pharmaceutical companies, pursuant to written antitrust guidelines, routinely avoid any discussions with competitors that could give rise to a challenge under the antitrust laws. Thus, even some limited discussions that may not themselves constitute antitrust violations may be hindered due to the risk that such discussions will be taken out of context by an antitrust plaintiff.

Each of the agreements described above could potentially be challenged by a private plaintiff or a government entity as antitrust violations. The fact that they were undertaken at the request of the federal government to bolster the country's defenses to a bioterrorist attack or as part of an emergency response to a bioterrorism event does not remove them from the reach of the antitrust laws. Courts have squarely rejected as being "without merit" a claim by an antitrust defendant that "in the emergency of war, the war power of the Federal Government and military

authorities takes precedence over the civil law and nullified the Sherman Act during the emergency.”¹

THE NECESSARY COOPERATION CANNOT OCCUR WITHOUT A SPECIFIC EXEMPTION

Opponents of a limited antitrust exemption for bioterrorism preparations typically question whether (i) the assistance requested by the government actually places the responding companies at risk of violating the antitrust laws or (ii) whether existing provisions for facilitating industry cooperative efforts may provide the necessary assurance. The answer to those questions are yes, an antitrust risk does exist, and no, existing procedures are not sufficient to remove that risk.

The first potential request for assistance described above relates to a government initiated survey of productive capacity. In theory, such information could be collected on a strictly bilateral basis by HHS and then only shared with industry, if at all, in an aggregated form. Trade associations routinely collect data in a similar fashion without violating the antitrust laws. The utility of such data, however, is limited because of the difficulty of comparing productive assets. HHS needs more than a series of historical production data from each company. To understand fully the industry's productive capacity, HHS needs to be able to compare each company's assets and assess how they might be used either alone or in conjunction with assets held by other companies in the fight against bioterrorism. Further, HHS needs to understand how existing assets dedicated to producing certain products could be expanded and/or converted to new uses. HHS cannot conduct such evaluations on its own. Rather, the companies may need to sit down together, under the auspices of HHS, to explore how they can each best contribute to the national defense.

Another area of potential cooperation that would raise antitrust issues includes discussions of which research areas should take priority for a given company. The antitrust laws expect that each company will assess the likely profitability of a given line of research and individually plan its research focus accordingly. In the past, Congress has recognized that such an approach may not always result in the socially optimal result. For example, the legislation providing special incentives for the pharmaceutical industry to engage in research on “orphan drugs” for diseases that affect small numbers of people demonstrates that market incentives may not produce the drugs America needs. A similar situation exists here, although the problem is not the size of the potential market; a bioterrorism event could affect millions. Rather the problem is the, hopefully small, likelihood that such a market will ever develop and the possibility that companies may not pursue research on some of the threats. The pharmaceutical industry is willing to do the work to prepare for each threat identified by HHS, but it makes no sense for each company to attempt to pursue every area in which the government might request research. The antitrust laws would at least call into question, and likely prohibit, an agreement among the pharmaceutical manufacturers to allocate research efforts among potential threats or to suspend non-bioterrorism research projects if requested by HHS.

A third area of potential concern is the sharing of research results or production techniques to enable all participating manufacturers to take advantage of the latest technology. Such cooperation also may allow companies to avoid duplicating, possibly at government expense, unproductive efforts undertaken by other companies. In the normal commercial context, such process improvements are treated as competitively sensitive information and their sharing would raise a question as to whether impermissible collaboration is occurring. To obtain the most effective bioterrorism countermeasures possible, however, exactly that type of sharing may be required.

EXISTING ANTITRUST PROCEDURES REGARDING JOINT VENTURES ARE INADEQUATE

The existing procedures designed to facilitate cooperative conduct under the antitrust laws would not provide adequate protection for the activities described in the preceding paragraphs. The National Cooperative Research & Production Act of 1993 (“NCRPA”)² provides some protection for joint research projects, but does not provide actual immunity from the antitrust laws.³ Thus, companies may still be dragged into litigation by competitors or consumer groups seeking to second guess the government decision to draw on the industry's expertise.

¹ *United States v. General Inst. Corp.*, 87 F.Supp. 157, 163-4 (D.N.J. 1949).

² 15 U.S.C. §§4301-05.

³ A NCRPA filing limits the liability of the joint venture participants to actual (rather than treble) damages in certain circumstances and allows for the recovery of attorney fees by any defendants that prevail in actions found to be “frivolous, unreasonable, without foundation, or bad faith.”

Similar problems exist with a business review letter from the Antitrust Division of the Justice Department or an advisory opinion from the FTC. These procedures allow businesses to request a statement of the government's current enforcement intentions with respect to a proposed course of conduct. One notable shortcoming of this procedure is that it has no effect on the ability of private plaintiffs to bring suit. Furthermore, the Antitrust Division will only provide a business review letter for proposed, not on-going, conduct. The nation's anti-bioterrorism preparations could be held up while the Justice Department bureaucracy ruminates over the industry request. Finally, even if a favorable letter is issued, it constitutes no more than a statement of present intent; no immunity is conferred. The FTC advisory opinion process presents the same problems. The limited comfort offered by a business review letter or an advisory letter is simply not sufficient for companies to suspend their normal antitrust guidelines and participate in activities that could entangle them in costly investigations or litigation.

HISTORY OFFERS NUMEROUS PRECEDENTS FOR A LIMITED ANTITRUST EXEMPTION

The Supreme Court has repeatedly said that “[t]he Sherman Act reflects a legislative judgment that *ultimately* competition will produce not only lower prices, but also better goods and services.”⁴ In a time of national emergency, there may not be the time to allow for the competitive process to produce the mix of goods and services society needs. Accordingly, there is a long history of providing legislative exemptions from the antitrust laws in specific areas. For example, during World War II, the War Production Board, the entity that was responsible for coordinating the mobilization of the U.S. economy for war production, had authority to

certify to the Attorney General in writing that the doing of any act or thing, or the omission to do any act or thing, by one or more persons...is requisite to the prosecution of the war, [and] such act, thing or omission shall be deemed in the public interest and no prosecution or civil action shall be commenced with reference thereto under the antitrust laws of the United States or the Federal Trade Commission Act.⁵

During World War II, this provision was invoked in a number of areas, including the efficient production of railroad freight cars, conservation programs in the dairy industry, and the pooling of information regarding the manufacture of Lucite, a newly developed plastic important to the war effort.⁶

The War Production Board's power to grant exemptions from the antitrust laws was designed to alleviate industry concerns that they would incur antitrust liability from responding to government requests for assistance. In the 1930s, the major oil companies had become ensnared in antitrust litigation arising from their participation in cooperative ventures established by the National Industrial Recovery Act as a means of stabilizing the industry.⁷ Faced with a recent example of how participating in government sponsored programs could result in antitrust problems, both industry and government leaders sought a way to ensure full and effective participation by industry.

Perhaps the most pertinent example of an antitrust exemption granted for wartime needs concerns the development of penicillin. Penicillin had been discovered in 1928 by Alexander Fleming, but had not been put into widespread clinical use. One major problem was devising an appropriate manufacturing process for large-scale production. The War Production Board invoked the antitrust immunity provision quoted above to allow for the exchange of technical information regarding penicillin production among the various pharmaceutical firms participating in the program. A history of the penicillin program written by a scientist involved in the effort notes that “the free exchange of information made possible by the lifting of the U.S. antitrust law controls undoubtedly sped mass production during 1944-45” and that it may have even “led to increased competition among firms that might not otherwise have undertaken to manufacture the drug commercially.”⁸

⁴*National Society of Professional Engineers v. United States*, 435 U.S. 679, 695 (1978) (emphasis added).

⁵56 Stat. 351 § 12. The Attorney General was required to give public notice when a certificate was issued and report to Congress periodically on exemptions granted by the WPB under this provision, but the WPB procedure for initially invoking the exemption was designed for flexible and speedy implementation.

⁶See Harold L. Schilz, *Voluntary Industry Agreements and Their Exemption From the Antitrust Laws*, 40 VIRGINIA L. REV. 1, 4 (1954).

⁷See *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 170-77 (1940); Schilz, *supra*, at 2-3.

⁸Gladys Hoby, *PENICILLIN: MEETING THE CHALLENGE* (Yale Univ. Press, 1985) at 213.

Congress has also granted antitrust immunity in areas not involving national security where there was a perceived need for joint industry action. The Television Program Improvement Act of 1990 created a three-year exemption from the antitrust laws for the purpose of "developing and disseminating voluntary guidelines designed to alleviate the negative impact of violence in telecast material."⁹ Specific legislative exemptions also exist for associations formed solely to engage in export trade (Webb-Pomerene Act, 15 U.S.C. §§61-66), agricultural cooperatives (Capper-Volstead Act, 7 U.S.C. §§291-292), and negotiations between sports leagues and television broadcasters (Sports Broadcasting Act, 15 U.S.C. §§1291-1295).

One further existing statutory immunity provision merits mention. The Defense Production Act of 1950 allows the President, or his designee, to "consult with representatives of industry... and other interests in order to provide for the making by such persons, with the approval of the President, of voluntary agreements and plans of action to help provide for the defense of the United States..." 50 U.S.C. App. §2158(c)(1). Voluntary agreements formed under the aegis of the Defense Production Act are exempt from the antitrust laws assuming certain procedural provisions are followed. The Defense Production Act has typically been used for the production of military equipment, such as ammunition and armored vehicles.

While a useful example of the need for antitrust exemptions in this general area, the Defense Production Act does not adequately address the government's likely needs in the bioterrorism context. With respect to manufacturing efforts, the scope of the Act appears to be limited to "the expansion of productive capacity and supply beyond levels needed to meet essential civilian demand." Many of the bioterrorism countermeasures contemplated would be for civilian, not exclusively military, use. The Defense Production Act includes extensive disclosure provisions that may deter companies from sharing confidential information and that may not adequately protect national security interests. The Defense Production Act also contains detailed procedural provisions, including preapproval requirements even for consultations, that may prove too burdensome and that may cause intolerable delays in the bioterrorism context.

**THE PROPOSED EXEMPTION IS NARROWLY FOCUSED AND PROVIDES FOR APPROPRIATE
OVERSIGHT**

Under the proposed exemption, entities may engage in joint action related to anti-bioterrorism activities "for the purpose of, and limited to, assuring or expediting the development, production, distribution, or sale of [bioterrorism] countermeasures" without incurring any liability under the federal or state antitrust laws. The antitrust exemption extends no further than the specific cooperation necessary to respond to the threat of bioterrorism and specifically excludes "exchanging information among competitors relating to costs, sales, profitability, prices, marketing, or distribution" where such information "is not reasonably necessary to carry out the purposes of covered bio-terrorism activities."

The exemption requires the participating parties to file notifications of their joint activity with the Antitrust Division of the Department of Justice, the Federal Trade Commission, and the Secretary of HHS. The Attorney General, after taking into consideration the views of the FTC and HHS, can nullify the antitrust exemption in a specific instance by determining that exempting the joint action described in the notification would not further the public interest. The Attorney General must also provide public notice of the identity of the participants to an agreement exempted under this provision and the agreement's area of planned activity. This provision provides a second check on any possible anticompetitive activities growing out of cooperative ventures authorized by the Act.

Mr. BILIRAKIS. Thank you very much, Dr. Friedman.
Dr. Noble.

STATEMENT OF GARY NOBLE

Mr. NOBLE. Good morning, Chairman and members of the committee. I am Gary Noble, Vice President for Medical and Public Health Affairs at Johnson & Johnson where I sit on the Emergency Preparedness and Business Continuity Task Force. Prior to that, I spent 29 years at the Centers for Disease Control and Prevention working on infectious diseases policy issues and legislative affairs.

⁹Pub. L. No. 101-650 § 501, 104 Stat. 5127 (1990)

I am pleased to testify today on behalf of the Advanced Medical Technology Association or AdvaMed to express support of the President's Bioshield initiative and urge inclusion of medical technologies in the Bioshield legislation.

AdvaMed represents more than 1,100 innovators and manufacturers of medical technologies. Many of the technologies our companies manufacture or are developing are integral to rapid and effective responses to potential terrorist threats. As I said, AdvaMed supports Project Bioshield initiative, because it can focus attention on the critical needs and provide economic incentives for the public-private interaction to protect our Nation from bioterrorist threats.

We also strongly believe that Bioshield legislation should include all medical technologies, including devices, diagnostics, and health information systems, as qualified countermeasures and medical products for use in emergencies. Legislation should not limit, in our view, support for medical technology research and development activities alone.

The proposal submitted to the Congress by the administration provides discretionary authority for the Secretaries of HHS and Defense to identify specific countermeasures that would be appropriate for inclusion in the national stockpile. We believe the Secretaries should have the clear authority to consider all medical technologies in these determinations.

Technologies represented by our industry add critically needed prevention, detection and treatment capabilities. Let me just enumerate some of those. Diagnostic tests to determine who has been exposed or infected decide the most effective course of treatment and limit the number of additional cases. As the director of CDC once said, we can't fight the enemy if we don't know where it is; we have to have the diagnostic capabilities.

Specialized drug delivery devices that may extend vaccine supplies; drug safety technologies to protect the blood supply, a critical need in emergencies; health information systems which we have heard about this morning to track vaccine delivery and document adverse events and to help detect and track biological outbreaks; and decontamination and sterilization technologies to restore facilities to a contamination free state, which we here in Washington witnessed recently, or 2 years ago. That is why we strongly recommend that in drafting Bioshield legislation, the committee extend to the Secretaries the authority to consider all medical technologies for inclusion in the national stockpile.

The proposal submitted to Congress by the administration would also allow for the use of drugs or devices currently in development, if the Secretaries of HHS or Defense determined that they may be effective in detecting, diagnosing, treating or preventing a serious or life threatening condition in emergency situations. The Secretaries have the ability to consider all medical devices. They should have the ability, including, for example, 510(k) products for use in such emergencies.

Most diagnostic tests are reviewed through 510(k) process. A test approved to detect a specific bacterium or viral agent may be modified, for example, to detect a related bacterium or virus. Such a product could have a countermeasure application and, therefore, should be covered by this legislation.

In addition, as the committee works on Project Bioshield, we can also recommend that the committee be mindful of the problems that can arise during a crisis in getting medical technologies to patients. In the wake of a significant attack or disaster, it will be necessary to ensure that local providers have adequate medical supplies to care for their casualties.

AdvaMed has worked closely with other industry groups to develop a planning guide for State and local emergency planners concerning medical supply chains and logistics. A prototype of this has been distributed and was mentioned earlier this morning.

AdvaMed is also concerned about business continuity and the potential vulnerability of facilities that may be the sole manufacturer of certain critical medical supplies. If these sites were to be incapacitated for whatever reason, supplies essential to quality health care may not be available when and where they are needed. We would, therefore, recommend that in the legislation the Secretaries of HHS and Defense be asked to consider the need to stockpile additional inventory of these critical supplies that may be manufactured by only one or two manufacturers.

Mr. Chairman, thank you for holding this hearing today. AdvaMed strongly supports the public-private partnership that Project Bioshield creates. We believe that harnessing the creative abilities of both the public and private sectors will be necessary to effectively address the bio-terrorist threats that we may face.

We believe Project Bioshield will allow the public to benefit from the prevention, detection, and treatment capabilities our industry can provide. AdvaMed stands ready to work with your committee to ensure the enactment of Bioshield legislation consistent with our testimony. I am happy to answer any questions.

[The prepared statement of Gary Noble follows:]

PREPARED STATEMENT OF GARY NOBLE, VICE PRESIDENT OF MEDICAL AND PUBLIC HEALTH AFFAIRS, JOHNSON & JOHNSON ON BEHALF OF THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION

On behalf of AdvaMed's (the Advanced Medical Technology Association) Medical Technology Preparedness Council, I am pleased to provide testimony in support of Project BioShield. My name is Dr. Gary Noble and I am Vice President for Medical and Public Health Affairs at Johnson & Johnson, where I serve on the company's Emergency Preparedness and Business Continuity Task Force. I also spent 29 years at the Centers for Disease Control and Prevention working in the areas of infectious disease, public policy and legislative affairs.

Johnson & Johnson develops a wide range of health care products, including devices, such as surgical supplies, diagnostic instruments and assays, and products used to ensure the safety of the blood supply.

AdvaMed represents more than 1,100 innovators and manufacturers of medical devices, diagnostic products and medical information systems. Our members produce nearly 90 percent of the \$75 billion in health care technology products consumed annually in the United States and nearly 70 percent of \$170 billion purchased around the world annually. Many of these technologies—such as rapid tests to diagnose diseases caused by bioterrorism, gels and foams that can rapidly close wounds, bioengineered skin products for burn victims, and information systems to communicate critical public health information—form an important part of a timely, effective response to terrorist attacks.

ADVAMED'S MEDICAL TECHNOLOGY PREPAREDNESS COUNCIL

In response to the events of September 11, 2001, AdvaMed established the Medical Technology Preparedness Council to assist federal agencies in ensuring that the health care delivery system is fully prepared. The Council, established in October 2001, meets regularly to discuss issues and concerns, and has begun to work with

key government preparedness entities including the Office of Emergency Preparedness (OEP), the Secretary's Command Center, the Food and Drug Administration (FDA), the Metropolitan Medical Response System (MMRS), and with individuals at the Centers for Disease Control and Prevention (CDC) who were administering the Strategic National Stockpile, among others.

We strongly support the principle of a public-private partnership in the area of preparedness. AdvaMed sponsored a sold-out conference on February 6, entitled "Innovation for Preparedness: the Public-Private Partnership," to strengthen the partnership between the government and the private sector on preparedness and to connect medical technology innovators with appropriate federal preparedness entities. Representatives from key preparedness entities within the federal government, including OEP, CDC, FDA, the Department of Defense, the National Institute of Allergy and Infectious Diseases (NIAID), the Department of Defense, the U.S. Army Medical Research Institute of Infectious Disease (USAMRIID) and the Environmental Protection Agency participated in the conference.

MEDICAL TECHNOLOGY: KEY TO RAPID AND EFFECTIVE RESPONSE

Many of the technologies our companies manufacture or are developing are integral to a rapid and effective response to any potential terrorist attack, including among others:

- **Diagnostic Tests:** In November 2001, Roche Diagnostics and the Mayo Clinic announced the development of a new rapid anthrax test that can detect anthrax in humans in an hour and quickly made the test available to public health agencies and hospital and reference laboratories. Companies are working to develop diagnostic tests for other bioterrorist infectious agents, including smallpox. AdvaMed and its companies are also working cooperatively with FDA and the CDC to speed development of a diagnostic test for West Nile virus.
- **Vaccine and Drug Delivery Devices:** "Microdelivery" devices in development by BD will deliver vaccines more efficiently and effectively, allowing better absorption by the body and at the same time extending vaccine supply. For example, in collaboration with USAMRIID, researchers have shown that use of these skin-based microdelivery technologies can significantly improve the performance of next-generation recombinant protein vaccines against anthrax and the organism that causes toxic shock.
- **Biochemical Decontamination Technologies:** We saw the importance of technologies to decontaminate large contained areas and their contents, sensitive electronic equipment, mail and other items after the anthrax attacks of 2001. STERIS Corporation and the U.S. Army Edgewood Chemical Biological Center have entered into a collaborative research and development project to evaluate, optimize and modify STERIS's Vaporized Hydrogen Peroxide (VHP®) technology and to demonstrate its effectiveness against biological and chemical warfare agents.
- **Blood Safety Technologies:** Companies continue to work on technologies to protect our blood supply through inactivation or pathogen removal technology to inactivate or eliminate blood-borne viruses, parasites, lymphocytes and bacteria from blood products.
- **Advanced Burn and Wound Care Technologies:** Companies have developed gels and foams that can rapidly close wounds and bioengineered skin for the treatment of second and third degree burns. On September 11th 2001, Smith and Nephew, Inc. employees personally drove bioengineered skin products to New York City and Washington, D.C. to ensure patient access to these critical technologies despite the disruption to the distribution and supply chains because of U.S. airspace closures.
- **Health Information Systems:** Coordination of information by local, state and national public health authorities is key for managing efficient immunization activities and detecting biological outbreaks. Specialized vaccination tracking systems being developed by BD and others can help document and manage adverse events to vaccines while assuring rapid, safe vaccine deployment. As a measure of the critical role health information systems can play, last Friday, the Department of Health and Human Services (HHS) announced that it will begin testing a system using handheld personal digital assistants (PDAs) for transmitting urgent information about biological agents to clinicians. The three-month pilot test is designed to gauge the best ways for federal officials to communicate effectively with front-line clinicians in the event of a bioterrorist attack.
- **Basic Medical Technologies:** Basic medical technologies are also essential during times of crisis including ventilators, imaging technologies and infusion and

monitoring equipment among others as well as gowns, gloves, masks and respirators to protect health care workers. A November 2001 JAMA article co-authored by Anthony S. Fauci, M.D. attributes the reduction in mortality in the inhalation anthrax cases to technological advances in diagnostics, imaging, microbiology, antibiotics and critical care.

ADVAMED SUPPORTS PROJECT BIOSHIELD

AdvaMed strongly supports the Project BioShield initiative. Recent media reports confirm that some terrorist groups have the willingness to use bioterror agents and have been trying to develop the capability to launch infectious agents. Additionally, the rapidity of the global spread of severe acute respiratory syndrome (SARS) highlights the vulnerabilities we face.

Specifically, AdvaMed's Council supports provisions in Project BioShield that will:

- Speed research and development on biomedical countermeasures by streamlining current NIH processes and providing funding for the construction and improvement of facilities needed to safely support research and development of countermeasures;
- Provide necessary funding to purchase biomedical countermeasures for the stockpile particularly those countermeasures determined not to have commercial markets; and
- Allow the Secretary to make promising treatments available in an emergency, even for those products that do not yet have full FDA approval.

PROJECT BIOSHIELD SHOULD INCLUDE ALL MEDICAL TECHNOLOGIES

Qualified Countermeasures. It is critical that all medical technologies—including devices, diagnostics and health information systems—be eligible for inclusion in all aspects of Project BioShield. The proposal submitted to Congress by the Administration provides significant discretionary authority for the Secretary of HHS to identify specific countermeasures to threats that would be appropriate for procurement and for inclusion in the national stockpile. The Secretary must annually determine whether such countermeasures have a significant commercial market other than as homeland security countermeasures. The Secretary should have the clear authority to include all medical technologies in these determinations.

While many focus on vaccines as the sole countermeasures needed to counteract bioterror agents, as we saw with the inhalation anthrax cases and are seeing again with SARS, the ability to diagnose individuals to determine who has been exposed is essential to treatment and to limiting the contagious spread of infection. Additionally, in the case of the anthrax attacks in the Senate Hart Building, the Brentwood Postal facility and others, as manufacturers continue to develop rapid tests like the Roche-Mayo Clinic anthrax test, they hold the promise that many individuals will be able to forego prophylactic antibiotic or other treatment. And as diagnostic tests advance, we will be able to detect those who have been exposed and are infectious yet are not exhibiting any signs of illness—as some are speculating is the possibility with SARS.

In the event of a bioterrorist attack, it will be critically important to ensure that all of the elements essential to treatment—diagnostic tests, specialized syringes and needles to deliver vaccines, information systems to assure safe and rapid vaccine deployment, and more—are delivered along with the vaccines. We strongly recommend that in drafting BioShield legislation, the Committee extend to the Secretary the authority to consider all medical technologies, including devices, in determining what technologies are needed to protect our nation from potential bioterrorist events.

Medical Products for Use in Emergencies. The proposal submitted to Congress by the Administration would extend authority to the Secretaries of HHS and Defense to declare a national, public health or military emergency justifying the authorization of a drug or device if they determine that it may be effective in detecting, diagnosing, treating or preventing a serious or life-threatening condition. They must also determine that the known and potential benefits of the product outweigh the known and potential risks of the product and that there is no adequate, approved and available alternative.

The Secretaries should have the ability to consider all medical technologies for use in emergencies. For example, most diagnostic tests are reviewed through FDA's 510(k) process. A test approved to detect a specific bacterium or viral agent may be modified to detect another bacterium or virus of the same family. FDA's 510(k) process recognizes that diagnostic test development is an iterative process that builds on the knowledge gained from the previous infectious agent to develop tests for similar agents. Thus, it is conceivable that a previously approved diagnostic test

may also prove to be useful in screening some bioterrorist agents. The value of this process is not limited to diagnostic tests but is the mainstay of all 510(k) products.

We strongly recommend that the Committee draft legislation that is broadly inclusive of all medical technologies, including 510(k) products. In the event that a product might have a needed countermeasure application, it should not be excluded because of a technicality.

NEED FOR STRONG LIABILITY PROTECTIONS

AdvaMed encourages the inclusion of strong liability protections for all aspects of Project BioShield, including medical devices. Presumably, those products that are declared qualified countermeasures under Project BioShield would also be declared qualified anti-terrorism technologies under Section 861 of the Homeland Security Act and would thus be eligible for the liability protections of that Act. However, it is not clear that companies whose products are declared for use in national, public health or military emergency situations would be eligible for the Section 861 protections. Such products, by definition, have not yet been reviewed or approved for use by FDA. Liability concerns will be a key consideration for companies manufacturing both qualified countermeasures and emergency-use products and the legislation should make clear that the liability protections of Sec. 861 of the Homeland Security Act apply to such products.

IMPORTANCE OF ASSURING ADEQUATE SUPPLIES IN THE EVENT OF A SIGNIFICANT ATTACK

As the Committee works on Project BioShield and assuring the availability of medical technologies to protect and treat patients, we also recommend that the Committee be mindful of the problems that can arise during a crisis in getting these technologies to patients. In the wake of a significant attack or disaster, it will be necessary to ensure that local providers are adequately supplied with appropriate medical equipment to care for casualties. As part of the AdvaMed's preparedness efforts, we have invested significant time and resources in working with the appropriate federal authorities to ensure that the needed medical materials and supplies will be available.

There is a critical initial period of 12-24 hours during which most supplies will come from local stocks in hospitals, other health care facilities, and local distributors. However, after that initial period, there will be a need to resupply these facilities. Local planners in particular seem to take the approach that "if it is needed, it will appear." AdvaMed has worked with Office of Emergency Preparedness and MMRS regarding the logistics of moving medical supplies to the scene of a major attack. Our objective has been to make planners at all levels aware of the issues around resupply and to provide advice about who to contact for resupply.

AdvaMed has worked closely with related trade associations, the Health Industry Distributors Association (HIDA) and the Association for Healthcare Resources and Materials Management (AHRMM) to develop a planning guide for state and local emergency planners that explains medical supply chains and logistics. The guide is currently being printed and details are being worked out for the physical distribution to members of the National Emergency Management Association (NEMA), the Association of State and Territorial Health Officials (ASTHO), and the National Association of City and County Health Officials (NACCHO). A prototype of this booklet is attached for your information.

AdvaMed has also supported the efforts of the AHRMM, HIDA and the Health Industry Group Purchasing Association (HIGPA) in the development of supply formularies. The formularies, which vary depending on whether the incident is chemical, biological, radiological, explosive, etc., are intended to act as a benchmark for emergency supply preparedness. They can be customized to meet the individual needs of hospitals and the communities they serve.

AdvaMed is also concerned about "business continuity" and the potential vulnerability of certain sites that manufacture critical medical supplies. These sites may be the sole source for certain supplies. If these sites are incapacitated for whatever reason, critical supplies essential to quality health care may not be available. Ways to address this dilemma include establishment of alternative site manufacturing capacity as well as stockpiling additional inventory. We recommend that the Committees consider this issue and that the Department of Homeland Security's Office of Information Analysis and Infrastructure Protection be charged with examining solutions that would provide incentives for industry to create back-up capacity or such other solutions as may be appropriate, including use of the Strategic National Stockpile.

CONCLUSION

We thank the Chairman for holding this hearing today and we appreciate the opportunity to provide testimony. During this time of national crisis, the Medical Technology Preparedness Council stands ready to work with the federal government to achieve our mutual goals of defending the homeland from terrorist attacks and providing the best medical care possible for our citizens. We also look forward to working with the Committee to assure the enactment of BioShield legislation consistent with our testimony. I would be happy to answer any questions that the Committee may have.

Mr. BILIRAKIS. Thank you very much, Dr. Noble.

Thanks to all of you. The Chair yields to Mr. Cox, the chairman of the full select committee, to inquire.

Mr. COX. Thank you, Mr. Chairman, and thanks to members of our panel for your illuminating testimony. I am going to address just a few questions to the entire panel, and leave it to your discretion who wants to jump in and answer.

Does anyone have a concern with the adequacy of the liability protections in the legislation as drafted? Dr. Read?

Mr. READ. The issue of product liability is very important for companies that are analyzing the risk and reward of getting involved in a long term research program for countermeasures. So both investors in those companies and their managements are going to be looking at this issue.

In some sense, it is just a cost of doing business. There are some sectors in our economy where we don't expect any special help or treatment, but in the case where the market is uncertain, and Bioshield is going to take some important steps to improve that, and in cases where there is not—where the products are unknown and may be used in a setting that is really quite outside the usual posture toward balancing risk and benefit, as we do in our civilian lives, and finally in a setting where the sponsors of a company may actually have very little control over how the thing they produce is actually used, because it may be in a government stockpile and used under emergency powers and so on as envisioned here, these are all situations which raise the importance.

So as I understand the way this legislation is drafted today, it could use extension to products that would be procured under this, and in the R&D phase we have some coverage, but I think the emergency use and actually following procurement and then in use, I think this needs to be extended.

Mr. COX. Dr. Noble.

Mr. NOBLE. I would simply add that I think that the liability needs to be inclusive of the broad range of medical technologies, particularly those that have been mentioned that are not yet approved. Companies are going to be very reluctant to enter into the marketplace or even into an emergency situation without some knowledge that there is a ceiling, some protection for not only the pharmaceuticals and vaccines but for the broad range of products that may be developed just for an emergency situation.

Mr. COX. In the paradigm situation, assuming that this Bioshield proposal becomes law, can you tell me whether or not firms would be interested chiefly in having the government finance the R&D or rather whether the firms would be interested in being paid at the completion of the R&D successfully and the delivery of a vaccine, serum or what have you?

Mr. FRIEDMAN. If I may respond, Congressman, I don't think there is a single model that I am prepared today to say is the preferred model. The factors to recognize are the ones that you are dealing with, which is recognizing that the vast majority of good ideas that begin testing ultimately fail, not because people are not well intentioned, not because the scientists are not devoted or the equipment is the best. It is because of our imperfect understanding of biology and medicine that these things fail. Either they are not effective enough or they are unacceptably toxic.

We know those are the risks inherent in developing any medicine, and they are certainly true for these bio-terrorist or infectious disease risks as well. There are costs associated with those research activities, how one defrays those costs. Is it done as the research continues? Is it reserved at the end in terms of recouping that?

There are a variety of different ways of doing it. The sensitivity is just that—we along with others are interested in engaging with you and the administration in thinking about the best way to deal with these very substantial problems that are not going to change within the foreseeable future. Our knowledge isn't going to suddenly get better, unfortunately.

Mr. COX. Dr. Read.

Mr. READ. I think that is a very important question, but I would consider rephrasing it. It is really not what the companies want. It is what we want, and what is the best way to get what we want as a society.

Mr. COX. If I may stick with my original question, the reason I put it that way is that we are moving this legislation because there are certain things that we want that the industry isn't in a position to provide without the bill.

Let me just disclose the premise for the question, which is my understanding of the biotech industry which is heavily represented in my district. In fact, in southern California and in Orange County, in particular, we have the preponderance of this activity in the country. I did a lot of work in the venture capital area for about a decade before I came to government.

My understanding of this industry is that it operates on long lead times and that it burns a lot of cash, and that there is a lot of unrequited investment, and that once in a while you are fortunate and you can pay back all of the other stuff. That being the case, it doesn't seem to me that a paradigm built into any legislation that we would write that has you paying for all the R&D and hoping to get lucky 5 or 10 years from now is what we should expect, really, to see, and we want to make sure the legislation works in the other paradigm, which is pay as you go, as it were.

That is my premise, and I need to be corrected if I am mistaken.

Mr. BILIRAKIS. Well, but very brief responses to that, please.

Mr. COX. Dr. Read and Dr. Baker. Mr. Chairman, I am finished asking questions. So I will just—

Mr. BILIRAKIS. All right. Very brief responses. Dr. Read, Dr. Baker.

Mr. READ. Just briefly, if we focus a lot of money on the R&D support, we will get companies gyrating toward being R&D producing companies, and if we focus more on the end result, we will

get companies focusing on delivering products on the shelf ready to be used.

It is true that the middle stage of these biotech companies is the hardest part to fund. It is easy to fund the beginning, because it is cheap. It is easy to fund the end, because the goal is in sight. But if we make that goal clear and valuable and the market is working, then investors will fund the middle. We need a mix.

Mr. BILIRAKIS. Dr. Baker.

Mr. BAKER. Very briefly, the FDA approval process is different for bio-threat agents. You have to do human toxicity testing in parallel with animal efficacy testing. Clearly, if you have a dual use drug, most companies will take on the human use applications anyway. That is part of their process.

I think where you need to move in is when you have testing that goes specifically for an application or development that goes for a specific application where there is no benefit to a company. There I would agree with some of the people that suggest that maybe the government could take that testing internally and use the drug and provide some type of royalty back to the company for developing it for these applications, along with alleviating the company of liability concerns.

Mr. BILIRAKIS. The gentleman from Ohio, Mr. Brown, to inquire.

Mr. BROWN. Thank you, Mr. Chairman. Dr. Friedman, nice to see you again. Thank you for joining us.

Do you have any concerns regarding BIDOL, the Act which promotes technology transfer and returns the government—and retains for the government the right to use technologies developed with government funds? Do you think changes to BIDOL should be part of this proposal?

Mr. FRIEDMAN. I am certainly not prepared to answer an important question like that today. I think the issue that you are raising is an extremely valid one, which is science today, more than ever before, is a collaborative activity and, in order for us as citizens to get the most of that, how do we promote the best exchange between Federal agencies, academia, and industry.

The precise dimensions, the characteristics of that, I think, deserve careful thinking, but today I am certainly not representing a position from PhRMA that can address that.

Mr. BROWN. Okay, thank you. I have heard from both sides of the aisle and both committees, Commerce and Homeland Security, a real concern, as I said, bipartisan concern about the government retaining some of those options because of the ultimate cost of all this, and much of the research done by NIH, much of the research done in some cases even by smaller entities like Walter Reed, that the taxpayer's share and not just the wondrous new drugs that can protect us from not just bioterrorism but other infectious disease, but that the taxpayers also get something for their dollars beyond the new drug, gets some savings in either the cost of some royalties going back to the government for a drug benefit or whatever it might be.

Dr. Baker, thank you for joining us. How do we improve Bio-shield to better encourage university involvement?

Mr. BAKER. Well, I think there are a number of issues. One is to enhance the research transfer over to universities. I think one

of the issues is it is not defined whether or not this would be in addition to the funding that is already provided through NIAID. It is also clear from the NIAID's current \$1.7 billion budget how much of that goes to universities and to the external program.

So having some perspective on what is going to be involved with this and how it can be used for infrastructure to enhance basically your research base in the universities is important.

The second thing, I think, is there are liability concerns for universities. Universities, I think, in many ways under BIDOL would be happy to provide the government back all the rights for their applications in this. They don't view these as commercial development that they can benefit from in the long term, and they are very hard to tech transfer. But there have been liability issues raised where universities have been sued with technology they have provided to companies or to other entities. So that is another issue that needs to be resolved for the universities.

So those are two major issues I think would help encourage universities to participate in this.

Mr. BILIRAKIS. Would the gentleman yield?

Mr. COX. Certainly.

Mr. BILIRAKIS. Certainly, on the liability—well, let's put it this way. I support the concept of what we are trying to do here. People have said some improvements have to be made. I think they have been acknowledged. Mr. Cox, others, have acknowledge that.

You know, gentlemen, we are at war, and an awful lot of people are sacrificing, certainly those who have men and women in harm's way right now. But we are at war, and I would hope that whatever we do here is—well, let's just put it this way. I would expect pharmaceutical companies to be cooperative in terms of what is needed in order to fight this war, particularly on the home front.

What we can do to help toward that end, fine, but if we don't do the job perfectly, I still would hope and expect and have confidence in our pharmaceutical companies, biotech people, what-not, to do the job. Do you have any comment in that regard? Dr. Friedman, you are sort of chomping at the bit.

Mr. FRIEDMAN. I'm sorry to—That is why I don't play poker, I guess. I think your point is exceptionally well made. I have spoken directly with the CEOs of many of the PhRMA member companies, their scientific directors, and many of their staff. The passion that they feel—It's a sort of a scientific patriotism, especially stimulated by the events of 9-11, especially stimulated by anthrax.

The irony is that we as a Nation have been challenged in the one area where arguably we have the greatest national strength, our biomedical science. Because of NIH, because of academia, because of industry, this is one of our national treasures, and the people who are involved in day to day working in this area feel so committed to wanting to make contributions in this. We share that concern.

So please don't misunderstand any of the suggestions, any of the issues that are raised, any of the constructive criticisms that are being offered as any reluctance to support in a general patriotic way what the Nation needs. What we are talking about is getting the biomedical defense that we as a Nation deserve, and we are trying to optimize that.

There are many different ways of doing that. I wouldn't presume to say that we have all the areas understood or covered, but there is enormous goodwill and interest.

Mr. BILIRAKIS. Thank you, Doctor. I'm on my own time now. Dr. Read, please, proceed.

Mr. READ. I would just like to echo those comments from Dr. Friedman. Many, many biotechnology executives and their investors, I know, are asking themselves today, you know, how can we help. Part of what motivates me is that this problem is both very urgent and very long term.

As long as our Nation is distinguished by its wealth and its influence from others, we are going to be a particular target, and part of what we are doing today is confronting the challenge of laying the ground work, the economic policy ground work for an industry that doesn't exist today, a biodefense industry.

We need to start thinking about some of the drivers that will build a healthy, properly supervised, properly overseen and productive industry, focused on the goals, not focused on the process. So we can depend on the patriotism of America's scientists and pharmaceutical and biotechnology researchers in the short run, but we should also be laying the ground work for a long term response to this important event.

Mr. BILIRAKIS. Yes. This is, of course, what we are trying to do. I appreciate those comments, and I know they come from the heart, and I trust that they reflect the views of the many institutions that you represent.

Mr. Thompson.

Mr. THOMPSON OF MISSISSIPPI. Thank you very much. We have talked and heard today about the government driving the market for some of the solutions. You gentlemen represent various aspects of the industry. Are you comfortable that, with the exclusive authority that Bioshield puts in the hands of the government, that they will in fact treat the selection of the companies to do the research fairly?

Mr. READ. If I could start on that, I think that a great deal of thought has gone into the bill and the intention about how to implement it, but we are in the early days of creating a policy and economic infrastructure, and there's bound to be some exploration as we go.

In the improvement and enhancements of Bioshield, I think we ought to look at some other mechanisms that have also been proposed, as in the bipartisan Lieberman-Hatch legislation that has been introduced. I think that there are things that we must explore, and I don't think that the Secretary or Dr. Fauci have had a chance. It is impossible for them to have fully thought through all the issues of how to deal with a fast follower.

Often the better product is the second product. There are intelligent mechanisms that could be put in place, and both the original innovator who has to pony up the money to be the pioneer and run the risk of getting all the arrows in his or her back, and somebody who might be motivated based on their research and their labs—you know, they think they've got a better way than the guy or whoever is in the lead.

These are tough issues, but they are issues that can be addressed by people of goodwill. This will should allow for a continued dialog between the administration and industry as we refine and explore some of these mechanisms.

Mr. BAKER. If I could also address another component of that question and also the chairman's question, I am a veteran of what, unfortunately, is now the first Gulf War. You know, being exposed at that point to agents that did not go through regular regulatory approval, and also administering them as a physician in the military, it raises concerns.

One of the things I would hope that doesn't happen in Project Bioshield—we see this 1 to 2-month timeframe that is laid up on the chart. I am not sure how that would achieve a product that I would feel comfortable putting into people in many cases.

It is not just choosing the companies that I think is important, but it is how you go about the process and how you make sure that, even though we are short circuiting some of the bureaucratic means of the regulatory process, we don't short circuit the safety means to a point where we cause more harm than good.

I think that is a big issue with this project, and I think it has been an issue already with the smallpox vaccine. So I have a concern in that regard.

Mr. THOMPSON OF MISSISSIPPI. Any of the other people care to comment?

Mr. FRIEDMAN. I think the tension that exists is trying to create a system that makes sure there is at least one company or one group of scientists pursue an important need and at the same time fostering competition, competition for the best ideas, for the best products, for the best price and so forth, and the two systems don't naturally link to one another.

You can design a system that will optimize one or optimize the other. What we are trying to do today collectively is to think about a system which will encourage for this large number of products, more than 50, I believe you and others have pointed out, that we will need in the relatively short time, how we at least have one good candidate in each of those areas while still trying to foster the sort of scientific competition that should exist to bring us the second and third and subsequent generation of even better products.

Mr. NOBLE. I would just say that I am sure that the government is interested in having as many suppliers as possible. So that if there is one that comes forward and the threat continues long term and there is a need to create a longer term stockpile, I am sure that the government—and based on some past experience, I know that they are not happy with a single vendor. So they will look for the opportunity to have competition or second suppliers.

Mr. BILIRAKIS. Thank you, sir. Mr. Shadegg, chairman of the Select Subcommittee.

Mr. SHADEGG. Thank you, Mr. Chairman. I want to thank all the witnesses for their thoughtful testimony. It seems to me, we are dealing with a very challenging problem here, and I think we have gotten some thoughtful testimony to that point.

I think it is fair to say that everybody agrees what we ought to try to achieve, but there are serious questions about how we get there. I want to focus on one in particular, not the issue of we get

one good drug and then we might have a better one later. I hope we get to the one good drug or the one good vaccine.

What I am worried about is the need to pass this legislation very, very quickly, contrasted with what I think is the biggest problem in the legislation, and maybe there are two. The biggest problem that I see is, I think, a genuine concern on the part of the Congress with what is completely open-ended in terms of its design, and unprecedented, and there has been discussion of that.

This funding is, in fact, mandatory and, if you heard Secretary Thompson in response to Chairman Cox's question who said, not only does the structure provide for unlimited funding over a scope of years, it was absolutely totally unlimited funding in a single year.

While I have a huge desire to get vaccines very, very quickly, I have a great deal of concern with that structure. Mr. Reed, or Dr. Reed, let me start with you. At page 3 of your testimony it says, "The scale of investment required is manyfold larger than implied by the current Bioshield proposal." I guess my question would be: I grant you that the scale of investment required is manyfold larger than we may be thinking about, but it seems to me it can't be larger than the funding contemplated by the bill, which is rather open-ended. I guess I want to give you an opportunity to clarify that point in your testimony.

Mr. REED. Well, I was reacting to the \$6 billion that has been described. That does seem to be enough, to me, over the time scale that I think is relevant. Again, we are laying the ground work for an industry that is going to make decisions and produce products that are going to protect our children and grandchildren. This threat is for the foreseeable future. I see it as, more or less, on the scale of strategic nuclear defense.

Mr. SHADEGG. I certainly agree.

Mr. REED. In terms of timing, sir. I don't want to comment on the specific legislative appropriation language that was used here. The key message for me as a venture capitalist, what am I going to be attuned to, is when this list of priorities has been set and an innovator out of a university has a great idea that may address that priority, will the customer be there? Can I count on the market?

The standard really: Is it, more or less, as predictable as civilian medicines are paid for today? It is not a perfect system. There are surprises, but the system we have is driven by data. There is a certain amount of predictability in how we get reimbursed. There is a certain amount of predictability about product liability and the regulatory environment, very important here.

If we could reproduce a semblance of that with respect—It is not a market failure. The market is just signaling to us that we haven't put these things in place in order for the market to operate.

Mr. SHADEGG. I would certainly agree with you that the \$6 billion may be way short of the mark. We in Congress have to look, however, at the overall structure of the legislation.

Let me ask a slightly different question. Your testimony is rather eloquent on focusing private sector investment and sending the right market signals to not only the companies that Dr. Baker represents but to the investors that you represent at least here today.

One of the things—I think Congress is going to look at a different funding structure than is currently proposed by the administration. I applaud the administration for trying, but I'm not certain that Congress is going to be comfortable with what is proposed.

Let me ask you a different point. It seems to me, at a minimum we have to fix the liability issue, because when you couple the question of are there appropriate market incentives with the issue of liability, that is a disincentive that we can, in fact, take out of the law. I guess I would like any of you to comment on that particular point.

Mr. FRIEDMAN. I think it is obvious that every intervention has side effects, and there will never be a perfect one that is uniformly effective and uniformly safe. So once we recognize that, then the question is how much information, how much confidence will the medical providers have when they offer an emergency innovation to a population under some bioterrorist threat?

The answer is it will never be enough. There won't be a large enough number of clinical trials done because of the nature of the products. The animal models that are used are going to be imperfect. So we are starting off with so many questions and so many unknowns that that is going to make it very difficult.

The second issue is it is going to be a very dynamic and confused environment when these products are likely used, and associating a side effect with an intervention is going to be particularly hard. So there are a lot of reasons to understand why that is going to be complicated, and I think the need, not only for companies but, as I implied before, for people who are providing the medications and the question of how to deal with those who are receiving the medications—there has to be some sort of umbrella structure which recognizes that we will be operating in an environment where we have much too little information, but the medical need is so great that we can't wait for more information.

Mr. SHADEGG. My time has expired. Anybody else who wants to could perhaps comment on that. But I want to make—Before I conclude, I want to make the point that, if you have thoughts on how this committee can create the proper incentives for industry to do what needs to be done and for investors to invest in any model different than what we are talking about in this legislation, an open-ended mandatory expenditure under which the Congress has no control whatsoever and which could open the door to what Congressman Cox talked about before, a future Secretary saying, gosh, I'd like to change this but it is law, I think that would help; because I think that would help us move this legislation forward quickly, which I think, clearly, the full panel wants to do.

Mr. BILIRAKIS. Yes. Dr. Read, and then we will go to Dr. Christensen.

Mr. READ. I think that there is room for a plurality of mechanisms, and I know it is hard for the government to work this way sometimes, but we may simply have to explore some different mechanisms in terms of their ability to get industry and our best people working on the right things at the pace we want and with the oversight and the sense of fairness that we need to feel comfortable. We just may have to explore some things.

One mechanism I think we ought to explore has been proposed and is gaining some serious interest with respect to global health in terms of producing vaccines for AIDS, malaria and tuberculosis, a purchase fund. If you could imagine a fund where people actually believe that the fund was there and it would stick to its promises and that, if you could hit a certain list of specifications of efficacy and safety and shelf life and pragmatism in terms of delivery in the field and so on, that was the target you're aiming for, you knew the customer meant it and was bound by it, I am sure that we could come up with a mechanism for those important diseases and probably countermeasures as well that would get the private sector probably far beyond—with the resources really beyond the government to invest against those goals, and there are all sorts of ways to deal with the fast follower and sharing the market that have been proposed.

I'd love to see some of that explored as part of this.

Mr. BILIRAKIS. Thank you very much. Dr. Christensen.

Ms. CHRISTENSEN. Thank you, Mr. Chairman. In the procurement of the countermeasures, it is somewhat dependent on the production and delivery of needed quantities within 5 years. Dr. Read, I thought I heard—you voiced some concern about the 5 years? If you could just elaborate on your concern, and I would like to know from you or from anyone what types of research might be excluded if we use that 5-year limit?

Mr. READ. I would say the 5-year limit excludes any vaccines where we don't have a good research lead, and many drugs. There are some things that could be done within the 5 years. Some very important devices, for example, and diagnostics are achievable, and there are some things in the pipeline now that could be done in that 5 years.

If we took away the exclusion of innovations that could be used in the private sector and have a private sector market, that expands the number of things that could be done in 5 years, because they wouldn't exist today if they weren't moving forward under some private sector, civilian use.

So we certainly don't want to penalize innovators who are heading forward with that. You might have a very good candidate for procurement under Bioshield simply because they might also have a smaller or even not so small dual use. We want to encourage that, not discourage it.

My experience with FluMist might be useful. In the 1960's a wonderful scientists at the University of Michigan, Dr. John Masab, invented a flu vaccine under Army sponsorship. It began clinical trials in the mid-1970's under NIH sponsorship. NIH courageously persevered. Tony Fauci was a great champion for this vaccine, and his team that worked on intramural-extramural, 20 years of clinical trials, and there was not a committed commercial sponsor until we decided that there was an opportunity for a commercial flu vaccine given by a nasal spray instead of a shot.

Perhaps you have heard about FluMist. This product is now at the FDA. We are hoping that it will be approved sometime soon. It is a company called MedImmune that we merged with that is carrying it forward, but this is now 36 years after its invention, 27 years after the first clinical trial, and 8 years after we first began

a committed commercial effort to bring it forward. So I think it gives you a sense that these timelines can be pretty long.

Mr. BAKER. You know, one of the big issues is you are right now making a research investment of \$1.7 billion at NIAID. I am sorry to inform you that it is highly unlikely that any of that will reach the stage that it will be Bioshield-able within 5 years. So you have to really look beyond that to recoup that research investment.

In fact, you need to help encourage that and transfer the technology over to the commercial sector effectively to recoup the research investment you are making.

Ms. CHRISTENSEN. That raises the other concern that I had, because I thought I understood from the Secretary's testimony and from my understanding of the bill that once those countermeasures are approved, they are exclusively to be used for bioterrorism.

A lot of us have voiced concern about the large output of funds that the Federal Government would have to expend in an open-ended fashion. How do you propose that we would change this legislation to accommodate a private sector use or other use for these measures after the Federal Government has spent so much money in developing them and procuring them?

Mr. READ. A couple of suggestions. One is I think we ought to delete the exclusion related to commercial use. In essence, what we are doing is we are punishing the innovator for being successful in finding a dual use. The government benefits when the technology finds a civilian use, because it means that production and all of these costs can be spread over both the civilian use and the bioterrorism defense use.

Some of our most important opportunities are broad spectrum antibiotics that could be used for serious hospital acquired infections for agents that produce—that are resistant, that may be very good agents against bio-threat agents. So I think that it would be important to leave that out.

I also think the 5-year restriction is also worrisome and that we should find a way to also make sure that these incentives are there for longer term projects.

Ms. CHRISTENSEN. Just a brief question that relates to the question I asked the Secretary. There are some possible amendments that might include requiring the product vendor to follow through to get FDA approval, which is one question I asked, or imposing requirements that specifically state who can distribute, who can administer the product, etcetera. Would that adversely affect—what is it called?—the push mechanism for these drugs? Anyone can answer.

Mr. READ. Well, maybe some others, but the more you decorate these requirements and the procurement with extra provisions, it just figures into the cost of doing business. I think the idea of having products get full FDA vetting is a very good idea. We just need to find the right way to build that in and still have the flexibility for the emergencies.

If we are looking for private sector investment, they will look at the whole picture, and they will look at the things that make it easier and more attractive and the things that make it harder and less attractive, and balance that. We are going to have to have

some flexibility here. We are not going to solve it all at this first bill.

Ms. CHRISTENSEN. I agree.

Mr. SHADEGG. [presiding.] The time of the gentle lady has expired. First, I need to encourage the witnesses to be short in their answers to further questions, because we are going to have to go to a vote. I call on the gentleman from Connecticut, Mr. Shays.

Mr. SHAYS. Thank you very much, Mr. Chairman. I would like to ask the witnesses first: Given that there can be altered—First, do you believe there can be altered biological agents?

Mr. READ. Absolutely. I think it is important to understand that all infectious agents are naturally altering all the time. So we have human manipulation, and naturally they are going to be modified.

Mr. SHAYS. Thank you.

Mr. BAKER. I would like to add, though, that the natural evolution can be remarkably short circuited by simple biotechnology techniques. There are in the literature techniques where over a week you can increase resistance to antibiotics by 64,000-fold, whereas it would take you billions of years to do that naturally. So this is a different event.

Mr. SHAYS. All right. Thank you. Do you believe that the concern of one of the witnesses before my National Security Subcommittee is a valid concern, and his concern was expressed by the fact that he said—He is a noted doctor of a major medical magazine. He said his biggest concern is that a small group of dedicated scientists could alter a biological agent that would have no antidote and could wipe out humanity as we know it.

Mr. BAKER. I do believe—and I serve on a DoD committee that reviews this—that altered organisms can present a remarkable threat, and not just physically altering or biotechnology altering a single organism, but releasing more than one organism at a time in a synergistic manner could have effects that are totally unpredicted by single or natural infections.

Mr. SHAYS. Do you think that this legislation addresses this issue?

Mr. BAKER. Well, this was the one point I tried to make. I think that, when you look at bio-threats as emerging infectious diseases, you miss the nuances that could be engineered into them or result from alterations in the amount of organism release or how it is propagated to individuals.

So, yes, I think they need to think of it more in the text of bio-threats agents and not as an emerging infectious disease.

Mr. SHAYS. Let me ask you this. Thank you. What is the private sector putting on the table for Project Bioshield? You all want R&D money, a guaranteed purchase price, and liability protection. What do you bring to the table?

Mr. FRIEDMAN. I can only represent the considerable activity that—

Mr. SHAYS. I wish you wouldn't sound so sincere. Sound a little more sinister or something. I can only—You have appeared before me too many times, Dr. Friedman. I'm sorry.

Mr. FRIEDMAN. You leave me speechless.

Mr. BAKER. While Dr. Friedman collects himself, it is the opportunity cost. I hear willingness among my colleagues in the biotech

industry to seriously sit down and put a thumb on the scale in favor of working on a serious countermeasure when they still have opportunities, important opportunities for—

Mr. SHAYS. That's a fair response.

Mr. FRIEDMAN. And let me just add that people are doing it now. You know, talk is cheap. I know of companies that are committing resources, scientists, laboratories, their best thinking now on some of these problems, without any of these guarantees. But the question is can we optimize that system?

The fact that we've got a few things moving forward, I think, is terrific, but we as citizens really want more.

Mr. SHAYS. Yes. I guess one of my concerns is that we are not throwing money at something where money might have already been spent, and that would be, you know, obviously, a concern.

Thank you, Mr. Chairman. I'll yield back. Thank you, gentlemen. Appreciate the answers.

Mr. SHADEGG. The time of the gentleman has expired. For the last set of questions, Mr. Green.

Mr. GREEN. I will be very quick.

Mr. SHADEGG. Just to give you a caution, we have exactly 9 minutes left.

Mr. GREEN. Okay. I have a number of questions, but I will submit them and appreciate the opportunity to do that. I would like to touch on one. Dr. Read or Dr. Baker, I know that I work with Baylor College of Medicine in Houston, and a lot of the research is being done by a lot of our great institutions, and I am aware of what is being done locally, and I am glad for this hearing to know what is being done elsewhere.

Let me ask one question, Mr. Chairman, and I will submit the rest. PhRMA's website states that the 2002 survey of medicines in development for infectious diseases found that the pharmaceutical and biological companies were working on 256 medicines for these diseases, including medicines for smallpox, anthrax, and the plague.

To follow up my colleague from Connecticut, if the industry is already taking steps to develop countermeasures for these products, is there really a need for this type of legislation?

Mr. FRIEDMAN. If I may respond, sir.

Mr. GREEN. Sure.

Mr. FRIEDMAN. If you look at the characteristics of those large number of medicines, many of them are for diseases that aren't seen as bio-terrorist threats. They are important diseases, hepatitis, childhood illnesses, and so forth.

The number of needs is vastly greater than 250, and the goal here is not to try and have protection in hand for every conceivable risk, because that won't be possible, but to try in a thoughtful, effective way to identify the highest risks and then to marshall the right science to address that.

Some of the things are being—Some of the threat agents are being addressed, but as was pointed out by committee members earlier, there is really an urgent need for new antibiotic classes and new immunologic modifications and new techniques for diagnosis and so forth. These are not being adequately addressed in the current environment.

Mr. GREEN. Thank you, Mr. Chairman. And I know we probably have only 7 minutes to vote now.

Mr. SHADEGG. We have about 7 minutes left, and we probably have to leave here at 5. So, okay.

Mr. NOBLE. I just wanted to add that there are many potential products in the diagnostic arena or other technologies, for example, agents that we haven't yet recognized. We now have SARS, and it probably occurs in a virus.

There are lots of things that are known, but there are a lot of things that aren't yet known, and we have to protect, diagnose and be able to take care of those threats as well, protect our blood supply if they are blood borne, for example.

Mr. GREEN. And I agree, and I understand the concern. In fact, I'm glad the Secretary mentioned about SARS because of the concern, because that is something that we need to address, particularly since the People's Republic of China—seems like they have drawn a wall there not to allow some information to be shared. Thank you, Mr. Chairman.

Mr. SHADEGG. I thank the gentleman for yielding back. I want to especially thank this panel for their superb testimony, but also for what you do on behalf of both my subcommittee of the Homeland Security Committee and also on behalf of Mr. Bilirakis's subcommittee. Mr. Bilirakis?

Mr. BILIRAKIS. Well, Mr. Chairman, thank you. Gentlemen, I know Dr. Friedman has been here before at least. We will have written questions to you. We would appreciate your responding to those when you receive them. Thank you so very much. Appreciate your patience.

Mr. SHADEGG. With that, we will conclude the hearing.

[Whereupon, at 12:50 p.m., the subcommittee adjourned.]

[Additional material submitted for the record follows:]

PREPARED STATEMENT OF KATHERINE BOWDISH, PRESIDENT AND FOUNDER, ALEXION ANTIBODY TECHNOLOGIES, INC.

Chairman Bilirakis, ranking member Brown, Chairman Shadegg, distinguished members of the Subcommittees, I am honored to present this testimony on the application of the very latest biotech solutions for defense against the very real threat of bioterrorism facing our nation today.

As we saw in the attacks against our nation in 2001, Inhalation anthrax is a highly fatal disease if not identified early enough for antibiotics to be of use. Death usually occurs within a few days of the onset of acute symptoms. The causative agent is *Bacillus anthracis*, and the lethality and short time course leading to death are due primarily to the effects of the toxin produced by the bacteria. Blocking the activity of anthrax toxin could provide time for appropriate antibacterial agents or the immune system to clear the infection. Anthrax toxins could be blocked at several stages in the process of toxin entry into the infected host cells. Such anthrax toxin antidotes might inhibit binding to the cellular receptor, processing of the toxin, or assembly of the toxin components on the cell surface prior to translocation of these molecules into the cell.

Antibodies are among the most logical and natural anti-toxins that could be developed for treatment of anthrax. There are two types of antibodies, monoclonal antibodies and polyclonal antibodies. Monoclonal antibodies are extremely effective, there is no risk of transmission of infectious agents, and the supply of antibody is unlimited as the cells can be continuously grown in culture. Polyclonal antibodies, on the other hand, are collected from a large pool of donors increasing the risk of transmission of infectious agents, and furthermore, the supply is limited by the number of donors available at any given time. Human or humanized antibodies have been proven to be safe and well tolerated for therapeutic purposes. Mouse monoclonal antibodies have been shown to neutralize (block) the anthrax toxin in

rats, and guinea pigs have been passively protected against anthrax infection using polyclonal guinea pig antibodies. Potently neutralizing human monoclonal antibodies to anthrax should therefore have therapeutic value in human anthrax infections.

Alexion Antibody Technologies, a wholly-owned subsidiary of Alexion Pharmaceuticals, has successfully isolated fully human monoclonal antibodies with therapeutic potential for biodefense. Using our proprietary technology, we have isolated fully human high affinity anti-anthrax toxin antibodies that show complete protection in animals against anthrax toxin challenge, as well as antibodies to other biodefense agents that we hope to test soon. We would be delighted to coordinate with government officials to see that our antibodies and our expertise are utilized for emergency stockpile generation to protect both civilian and military populations.

Specifically, we have used our proprietary technology to isolate fully human high affinity, potently neutralizing antibodies against anthrax toxin proteins. To do this, we cloned the genes encoding human antibodies from blood and bone marrow of vaccinated military personnel to create human antibody display libraries. Human antibody fragments that specifically bind to anthrax toxins were isolated from the library through a process termed "panning". A panel of human antibodies that bind anthrax proteins was generated. Antibody fragments were assayed for their ability to neutralize anthrax toxin activity in cell based assays.

Over 140 individual antibody fragments with strong binding activity were further characterized. Laboratory neutralization assays using the purified antibody fragments were performed, demonstrating that 17 of the first 21 anti-toxin antibody fragments in the first screens were able to block the effects of the anthrax toxin with greater than 80% protection from cell death. Five antibody fragments protect fully (100%) at this concentration.

Because two of the antibody fragments protect to 100% in cell based assays, they were chosen for testing in animals against recombinant anthrax toxin challenge. In these studies, the two antibody fragments protected fully allowing complete survival of the animals following anthrax toxin exposure.

To our knowledge, this work demonstrates for the first time that human anti-anthrax toxin antibodies that are potently neutralizing can be isolated from immunized donors. These antibodies, either alone or in combination, may be useful as immunotherapeutics at the onset or during the course of an infection and for the passive protection of unvaccinated personnel that might need to enter an area of suspected anthrax release.

The work described above has been discussed with and presented to a large number of scientific experts in anthrax, on other agents of bioterror, as well as experts in antibody therapeutics, and passive immunotherapy. In order to carry out the work initially, we described our approach to some of the worlds leading experts in anthrax at the United States Army Research Institute of Infectious Disease (USAMRIID). The willingness of the USAMRIID researchers to work with us by transferring needed materials, as well as having further discussions in person and by phone throughout the work lends support to our approach. On completion of the work, we drafted a manuscript describing our success in anti-toxin therapy and sent it to two of the worlds leading experts in antibodies and passive immunotherapy at The Scripps Research Institute, a world renowned institute for immunology research. These experts approved of the research and suggested submission of our work to a world class journal read by scientific leaders throughout the world.

In addition, in discussions of our approach to a leading botulinum expert at UCSF, the comments we received were how important the work was, how important it was that the researchers carrying out the work have the necessary capability and expertise, and how comforted he was that our company with its significant expertise was willing and able to take on the work. Furthermore, in discussions with the CDC, where we already have a program ongoing in biodefense against a different threat of bioterror, the lead CDC participant in that program reviewed the anthrax research and commented that it was clear Alexion knows what it is doing. Experts at each of the above agencies have either offered their assistance to further the work, or have agreed to participate with us whereby each offers their expertise toward a different agent of bioterror in the form of an NIH program project grant, or both.

Finally, when this work was presented at a large, open peer reviewed scientific meeting, the members of the audience of experts were excited by the developments, and encouraged that we would obtain appropriate federal government support to complete development through the next phases leading to emergency stockpile generation.

Alexion's biodefense program has been entirely internally-supported to date. We saw a need and recognized that we had the ability to offer our technology and exper-

tise. And most importantly, we have demonstrated success of our approach. It is our hope that Congress can help us ensure that the appropriate decision-makers in our federal government are aware of our critical and highly relevant work for consideration for civilian and military defense.

Building the necessary emergency stockpiles for civilian and military defense is certainly something that no one company can or should accomplish solely with private funding. Therefore, we are looking for assistance from the Federal Government through NIH for the final phase for development of these therapies. Our next goals are to test the current panel of anthrax antidote antibodies against live anthrax spore challenge in relevant animal models, manufacture the antibodies according to FDA guidelines, and do a Phase I safety study in humans. Importantly, Alexion has significant monoclonal antibody clinical development and manufacturing expertise. Alexion can build and run a government-supported manufacturing facility, or Alexion and a contract manufacturer can provide the needed material.

Our very successful and highly relevant work on anti-toxin therapy for anthrax exposure could quickly lead to the emergency stockpile needed for biodefense against anthrax. Further, we are currently applying the same technology to additional agents of bioterror in our research laboratories. Preliminary results suggest we will have similar successes with other bioterrorism agents, such as smallpox and plague, allowing us to proceed with desperately needed emergency stockpiles of antidotes to a wide range of bioterror agents. At the minimum, we hope our research will deter any would be terrorist, and alleviate public anxiety.

I thank the committee for this opportunity to present this testimony and welcome any written questions.

RESPONSES FOR THE RECORD OF DR. LEIGHTON READ, REPRESENTING THE
BIOTECHNOLOGY INDUSTRY ORGANIZATION

Question: Can you explain for the Committee the primary concern of the biotechnology industry regarding liability? And, what are your recommendations for providing liability protections that ensure the biotech industry will maintain a long-term commitment to this effort?

Response: BIO sees liability as a profound concern for private companies who may want to contribute to biodefense via R&D and production of countermeasures such as drugs and vaccines. There are striking differences between bioterrorism countermeasures and civilian biotechnology products that stem from:

- A. the nature of the target biology and medical need,
- B. the nature of the information that can be collected prior to use of a promising countermeasure,
- C. the likely role of government in recommending, distributing and administering countermeasures, and
- D. the unusual circumstances in which countermeasures may be administered.

A. While drugs and vaccines against infectious agents represent many of the enduring successes in pharmaceutical and biotechnology product development, biodefense is different. Agents that must be countered in biodefense range from natural pathogens delivered intentionally by surprising means (as in the case of mail delivery of anthrax) to microorganisms genetically engineered by our opponents to accomplish specific, but yet unknown pathology. The challenge is a man-made contest of offense and defense that does not have a clear parallel in drug and vaccine development for natural pathogens. For example, it is possible for agents to be designed with harmful features that are activated by the obvious countermeasures. Furthermore, for some potentially important countermeasures it may be difficult to distinguish the severe end of the drug side effect profile from the mild end of the biothreat pathology. These examples illustrate the kind of surprises that greatly raises the risk that an innovator might be held unfairly accountable for unexpected consequences to recipients.

B. Preclinical and clinical testing data obtainable for candidate countermeasures will typically be less complete than for drugs and vaccines targeting most human diseases. As acknowledged by the FDA's recently formalized animal testing rule, *human efficacy* data cannot ordinarily be obtained in advance of an attack with a dangerous bioweapon. This means that the key data supporting use is from animal studies of safety and efficacy and human safety studies. However, animal efficacy and safety work will often be constrained by the daunting logistics of conducting animal experiments under very high levels of biosafety containment. For some very serious threats, we must be prepared to stockpile countermeasures with significant known side effects

until a better countermeasure is developed. Because of the risk we will be asking experimental subjects to take, the number enrolled in such trials will be certainly be smaller than in civilian drug or vaccine development. The inherent limitations of the data package supporting use of many countermeasures, particularly when the Secretary of HHS determines that an "investigational" agent should be deployed, raises the risk that an innovator might be held unfairly accountable for unexpected consequences to recipients.

C. Under many of the scenarios in which a biodefense countermeasure is actually used in people, the government is taking a larger role than is typically the case for drugs and vaccines. Normally, a private company can initiate important decisions regarding changes in labeling and product recalls if it believes this is in the best interests of patients or the company. In the event of a biodefense emergency, it is reasonable to assume that private companies will have ceded control over the physical product and the distribution pipeline to government entities.

D. Companies will have much less ability to correct or adjust the messages to caregivers in the midst of an emergency. In case of a serious crisis, details of indications and contra-indications will almost surely be missed and the government may have to make last-minute changes in usage recommendations, possibly including *mandatory administration* to account for rapidly changing circumstances. This greatly increases the risk that an innovator might be held unfairly accountable for unexpected consequences to recipients.

At the same time that the risk of potentially enterprise-threatening litigation is increasing, the availability of adequate insurance to cover these risks is decreasing.

In enacting the Homeland Security Act, Congress recognized that the fear of facing extraordinary liabilities from third party suits could jeopardize the development of smallpox vaccines and therefore included provisions to protect companies involved in that effort. Similar protections are necessary for development of other countermeasures. Therefore, we have provided to the Committee staff proposed amendments to the Administration's draft legislation which would extend to manufacturers of other types of biomedical countermeasures protections provided by the Homeland Security Act to manufacturers of smallpox countermeasures.

Question In your testimony Dr. Read, you call for greater attention on market incentives or "pull" mechanisms. Since this is, undoubtedly, an atypical market, can you provide recommendations on how a guaranteed market can be created through BioShield and explain what is necessary for us to reach our objective of being successful in this arena?

Response: BIO has recommended that the Administration's proposal be amended to include provisions that require the Department of Health and Human Services to enter into an "Agreement to Purchase" biomedical countermeasures. The agreement would be contingent on a determination that the countermeasure is appropriate for procurement and would address, among other terms, the price, quantity and available market.

BIO's proposed amendments would provide more certainty that there will be a market when the private sector innovator succeeds in creating a product that meets public health needs. In the absence of an assured market as provided for in BIO's proposal, biotechnology companies will be extremely reluctant to undertake the expensive, lengthy and challenging process to develop new countermeasures.

Other "pull" mechanisms should also be explored under the BioShield authorizations. These policies are the first steps in creating a biodefense industry for the United States and some experimentation with procurement and incentives will be necessary. The Secretary of HHS should be given authority to use multiple contracting mechanisms appropriate to countermeasures having differing R&D challenges and product life cycles, as illustrated by vaccines, drugs, and diagnostics. BioShield clearly provides for contracting with specific companies to provide specific countermeasures. "Innovation prizes" are another "pull" mechanism that have been proven to stimulate vigorous private sector innovation in the past and should be available under BioShield.

The legislation should provide for a dialogue among government and private companies to develop contractual terms dealing with product specifications and market sharing in the event a fast-follower provides a better solution than the first to succeed. Internet reverse auctions where the customer names his or her "own price" for travel purchases suggest a mechanism by which the government can ensure that it is not paying more than necessary to attract willing innovators to the challenge, and—even more important—not paying enough to get a critical problem on the table.

The Secretary should be accountable to Congress for reporting on the success of different "pull" mechanisms so that these can be refined over time.

Question: As a physician and former biotech CEO experienced with vaccine development, can you outline for the Committee just how vaccines are made and what difficulties, if any, you envision regarding the development and production of countermeasure vaccines?

Response: Of the many pharmaceutical and biotechnology approaches that can be expected to yield bioterrorism countermeasures, vaccines have a spectacular track record of controlling infectious diseases, but vaccines often take more time to develop. Drugs for infectious agents typically exploit a specific biochemical weakness in the microorganism that is not found in humans. Vaccines intervene in the complex interplay between the pathogen and the human immune system where most of the detailed biology has yet to be worked out. While there are often good clues about how to begin and many potential vaccine technologies that may be exploited, the process still involves a great deal of trial and error. In many vaccine development efforts, researchers must deal with poor correlation among laboratory assays, animal testing, and actual protection in humans.

Vaccines are typically biological products, composed of complex protein mixtures or killed or weakened forms of the pathogenic microorganism. Manufacturing of these types of products are much more complex and expensive. The FDA regulates these products based largely on every little detail in the manufacturing process, because it is impossible to quantify every ingredient in the final product.

Development of biodefense countermeasure vaccines will share all of these challenges complicated, in many cases, by a lack of experience with the target agent and by the difficulty in performing experiments with such a potentially dangerous pathogen. Manufacturing of vaccines based on some successful technologies will also be uniquely expensive and complicated. Today's vaccines for tetanus and diphtheria are carefully extracted from large stocks of pathogenic bacteria and the flu shot is made by growing large stocks of virulent influenza, which is then inactivated in a rigorous manufacturing process.

QUESTIONS FROM HON. JOHN SHADEGG

Question: The Defense Science Board in its May 2002 Study on Defense Science and Technology has issued a challenge to DoD that by 2005, the pathogen to drug hit process should be reduced from years to months, by 2010 from months to weeks, and by 2020, it should have the ability to go from bug to drug within 24 hours. It has recommended spending \$200 million per year over the next twenty years to achieve this.

What is your opinion of the Defense Science Board's challenge on going from bug to drug within 24 hours by 2020?

Response: I haven't reviewed the DSB challenge in detail, but am impressed with the importance of its vision. Great scientific progress has often followed such a clear and quantitative statement of what needs to be done, as in the case of the prizes announced for early aviation pioneers and physicist Richard Feynman's challenge regarding ultraminiaturization that has spurred the imagination of many nanotechnology innovators.

These are extremely aggressive objectives that depend very much on how "drug hits" are defined. It is NOT out of the question that for certain types of pathogens and certain types of "drugs hits" that this might be achieved. For example, DNA sequencing and synthesis technology now on the horizon could conceivably permit the design and production of antibody-like molecules that could be turned around in these time frames.

Part of the value of this challenge is not just technical, but implies that we must be innovators in the way we regulate the balance of risk and benefit in the application of our technology. Posting a reward, in the form of a suitably specified commitment to purchase such a countermeasure technology would be the most effective spur to such innovation. The magnitude of the need for such a system would justify very attractive rewards.

QUESTIONS FROM HON. DAVE CAMP

Question: Two major issues in countermeasure technology development are economic incentives and liability concerns. In Secretary Thompson's testimony, he mentioned that grants and contracts might not be sufficient for developing the public/private partnership. How will Project BioShield address these issues in order to expedite the development of the next generation of countermeasures?

Response: Grants, contracts and other "push" mechanisms have a vitally important role to play in ensuring that effort gets underway in key technology areas for our biodefense. These are not the mechanisms that will ensure that products are produced for stockpile or use. An adequate market opportunity ("pull") will be re-

quired to draw in the large amounts of private capital and expertise necessary to complete the later stages of drug and vaccine production. There is not a convincing track record that the government or any other entity has been able to deliver finished products such as these. The inclusion of "pull" mechanisms in the Administration's BioShield proposal signal the importance of creating workable incentives for the industries capable of developing and producing countermeasures.

QUESTIONS FROM HON. EDOLPHUS TOWNS

Question 1) Given that devices, biologics and drugs usually have different standards on what makes a product commercially viable to make a commitment to R&D, does the BioShield proposal offer enough incentive for your individual industries? If I could get comments from each of the panelists on this issue.

Response: To the extent that the Administration's BioShield proposal includes liability protections and guaranteed market provisions, BIO believes that the environment to develop commercially viable biotechnology products will be significantly improved. BIO sees liability as a profound concern for private companies who may want to contribute to biodefense via R&D and production of countermeasures such as drugs and vaccines. In enacting the Homeland Security Act, Congress recognized that the fear of facing extraordinary liabilities from third party suits could jeopardize the development of smallpox vaccines and therefore included provisions to protect companies involved in that effort. Similar protections are necessary for development of other countermeasures.

BIO recommends that the Administration's proposal be amended to include provisions that require the Department of Health and Human Services to enter into an "Agreement to Purchase" biomedical countermeasures. The agreement would be contingent on a determination that the countermeasure is appropriate for procurement and would address, among other terms, the price, quantity and available market. In the absence of an assured market biotechnology companies will be extremely reluctant to undertake the expensive, lengthy and challenging process to develop new countermeasures.

Question 2) Do we need to add anything to this proposal to make it easier for academic research institutions and commercial companies to work together on developing these countermeasure products?

Response: It is important that the intellectual property environment provided by the Bayh-Dole Act be preserved in order to keep the door open for academic-industry collaboration. The Bayh-Dole provisions haven enabled countless technologies to move from the research stage into development, and commercialization.

Question 3) If each of you had a product already approved to treat a given, what incentives exist in this proposal or what would you like to see to encourage research for a new countermeasure?

Response: With respect to existing products that have already been approved for use, BIO's primary concern is the exposure to liability associated with the inherently risky nature of extending product use to conditions for which FDA approval was not granted. Again, such uses apparently would be conditionally approved by FDA based on less than the generally required amount of data. And, again, presumably consumers would either be required or strongly urged to use the medication for such purposes. Concerns about liability do not, therefore, differ substantially for new uses of products approved for other conditions than for countermeasures still under development. BIO recommends the inclusion of appropriate liability protections for companies engaged in this hazardous arena. Specifically, BIO has provided to the Committee staff proposed amendments to the Administration's draft legislation which would extend the protection already provided by the Homeland Security Act to manufacturers of smallpox countermeasure to the manufacturers of other types of biomedical countermeasures. BIO believes that such protection is essential to encourage commercialization of existing technologies and research in new countermeasures.

Question 4) If a better product is developed after you have signed a contract with the government, should the government be forced to stockpile your product—because you already have a contract—or does the government need the flexibility to go with the better product, which many mean canceling your contract?

Response: One of the most important features of BioShield is the attempt to create a credible and reasonably predictable market for countermeasures so that innovators will take risks in this area. No market is perfectly predictable and successful innovators are accustomed to taking competitive pricing risks, based on their experience in established markets. In the market for biodefense countermeasures, there is very little history and much of it is not encouraging. The government must be prepared to introduce some predictability in the reward structure. For example,

it is not necessary (or even a good idea) to stockpile a countermeasure found to be obsolete, but a successful innovator who took great risks in good faith and was the first to meet the government's a priori specifications should be able to count on a specific financial reward sufficient to justify the risk and opportunity cost of diverting effort to this problem.

Question 5) This bill appropriates unlimited sums of money. However, our Orphan Drug Program also gives incentives to work on R&D for diseases that are not that prevalent. And, many illnesses still have not cure. Is BioShield a research problem that money alone can solve?

Response: NO: LEADERSHIP is absolutely essential.

Money alone does not solve the potential problem of no supply, or short supply of biological countermeasures. However, these policies are the first steps in creating a biodefense industry for the United States and some experimentation with procurement and incentives will be necessary. The Secretary of HHS should be given authority to use multiple contracting mechanisms appropriate to countermeasures having differing R&D challenges and product life cycles, as illustrated by vaccines, drugs, and diagnostics. BioShield clearly provides for contracting with specific companies to provide specific countermeasures. "Innovation prizes" are another "pull" mechanism that have been proven to stimulate vigorous private sector innovation in the past and should be available under BioShield.

The challenge of discovering a cure for a number of orphan illnesses does not call for us to retreat solely because the cure has not yet been found. On the contrary, we must press forward even more to find the breakthrough. The biotechnology industry is at the forefront of pursuing therapeutics and vaccines to combat a number of illnesses that affect a smaller group of patients. Similarly, the threat of a biological attack that relies on a seldom used, but extremely dangerous, pathogen requires that we must be vigilant in our biodefense appropriations. That challenge implies that we must be innovators in the way we regulate the balance of risk and benefit in the application of our technology. Posting a reward, in the form of a suitably specified commitment to purchase such a countermeasure technology would be the most effective spur to such innovation. The magnitude of the need for such a system would justify very attractive rewards.

RESPONSES FOR THE RECORD FROM DR. GARY NOBLE, JOHNSON & JOHNSON

Question 1. Dr. Noble, you mention in your written testimony that people tend to overlook the contributions of medical devices when considering the countermeasures needed to combat bioterrorism. Why?

Response: While many focus on vaccines as the sole countermeasures needed to counteract bioterror agents, as we saw with the inhalation anthrax cases and are seeing again with SARS, the ability to diagnose individuals to determine who has been exposed is essential to treatment and to limiting the contagious spread of infection. There are numerous technologies that assist in or play a significant role in combating bioterrorism, including diagnostic tests. The ability to quickly diagnose individuals to determine who has been exposed is essential to treatment and to limiting the contagious spread of infection. Additionally, in the case of the anthrax attacks in the Senate Hart Building, the Brentwood Postal facility and others, as manufacturers continue to develop rapid tests like the Roche-Mayo Clinic anthrax test, they hold the promise that many individuals will be able to forego prophylactic antibiotic or other treatment. And, as diagnostic tests advance, we will be able to detect those who have been exposed and are infectious yet are not exhibiting any signs of illness.

Question 2. In your opinion, would medical devices qualify for funding under Project BioShield? If not, should they?

Response: The Administration proposal includes devices in portions of its BioShield proposal but excludes devices from key aspects of the proposal. Devices are clearly included in the Biomedical Countermeasure Research and Development section of the legislation. Devices are explicitly listed in the definition of that section. However, devices are excluded from the qualified countermeasures procurement section. The definition for that section lists only drugs and biologics.

The proposal, at least as initially drafted, creates the paradoxical situation in which a device company that cooperatively engages in research with the National Institute of Allergy and Infectious Diseases (NIADD) in the development of a product with no commercial market would be prevented from recouping its full investment because the Administration proposal prevents it from being purchased as a qualified countermeasure. Companies that did not develop a technology without the R&D as-

sistance of NIAID would similarly be prevented from recouping their investment because such products could not be purchased as qualified countermeasures.

The Administration proposal also prohibits devices that are reviewed through FDA's 510(k) review process from being considered for use in emergencies. Most diagnostic tests are reviewed through FDA's 510(k) process. It is not unusual for diagnostic tests that have already been approved to detect a specific bacterium or viral agent to be modified to detect another bacterium or virus of the same family. Thus, it is conceivable that a previously approved diagnostic test may also prove to be useful in screening some bioterrorist agents. FDA's 510(k) process recognizes that diagnostic test development is an iterative process that builds on the knowledge gained from the previous infectious agent to develop tests for similar agents.

AdvaMed strongly recommends that the legislation be drafted broadly to include medical devices, including 510(k) products, in all aspects of the BioShield program. The Secretaries of Health and Human Services (HHS) and of Homeland Security should have the discretionary authority to consider *all* medical technologies, including devices, in determining what may be needed or most useful in protecting our nation from potential bioterrorist events. Devices (including devices approved through the 510(k) process) that have needed countermeasure applications, should not be excluded from consideration due to a technicality.

Question 3. What types of devices are needed by the government to respond to a bioterrorist attack?

Response: There are numerous medical technologies that are integral to a rapid and effective response to any potential terrorist attack, including among others:

- **Diagnostic Tests:** In November 2001, Roche Diagnostics and the Mayo Clinic announced the development of a new rapid anthrax test that can detect anthrax in humans in an hour and quickly made the test available to public health agencies and hospital and reference laboratories. Companies are working to develop diagnostic tests for other bioterrorist infectious agents, including smallpox. In a related development, AdvaMed and its companies are also working cooperatively with FDA and the CDC to speed development of a diagnostic test for West Nile virus.
- **Vaccine and Drug Delivery Devices:** "Microdelivery" devices in development by BD will deliver vaccines more efficiently and effectively, allowing better absorption by the body and at the same time extending vaccine supply. For example, in collaboration with USAMRIID, researchers have shown that use of these skin-based microdelivery technologies can significantly improve the performance of next-generation recombinant protein vaccines against anthrax and the organism that causes toxic shock.
- **Biochemical Decontamination Technologies:** We saw the importance of technologies to decontaminate large contained areas and their contents, sensitive electronic equipment, mail and other items after the anthrax attacks of 2001. STERIS Corporation and the U.S. Army Edgewood Chemical Biological Center have entered into a collaborative research and development project to evaluate, optimize and modify STERIS's Vaporized Hydrogen Peroxide (VHP®) technology and to demonstrate its effectiveness against biological and chemical warfare agents.
- **Blood Safety Technologies:** Companies continue to work on technologies to protect our blood supply through inactivation or pathogen removal technology to inactivate or eliminate blood-borne viruses, parasites, lymphocytes and bacteria from blood products.
- **Advanced Burn and Wound Care Technologies:** Companies have developed gels and foams that can rapidly close wounds and bioengineered skin for the treatment of second and third degree burns. On September 11th 2001, Smith and Nephew, Inc. employees personally drove bioengineered skin products to New York City and Washington, D.C. to ensure patient access to these critical technologies despite the disruption to the distribution and supply chains because of U.S. airspace closures.
- **Health Information Systems:** Coordination of information by local, state and national public health authorities is key for managing efficient immunization activities and detecting biological outbreaks. Specialized vaccination tracking systems being developed by BD and others can help document and manage adverse events to vaccines while assuring rapid, safe vaccine deployment. As a measure of the critical role health information systems can play, HHS announced that it will begin testing a system using handheld personal digital assistants (PDAs) for transmitting urgent information about biological agents to clinicians. The three-month pilot test is designed to gauge the best ways for federal officials to communicate effectively with front-line clinicians in the event of a bioterrorist attack.

- **Basic Medical Technologies:** Basic medical technologies are also essential during times of crisis including ventilators, imaging technologies and infusion and monitoring equipment among others as well as gowns, gloves, masks and respirators to protect health care workers. A November 2001 JAMA article co-authored by Anthony S. Fauci, M.D. attributes the reduction in mortality in the inhalation anthrax cases to technological advances in diagnostics, imaging, microbiology, antibiotics and critical care.

Question 4. In the “emergency use” portion of BioShield, unapproved devices subject to premarket approval could be used to respond to bioterrorist attack, when the benefits of the device outweigh its risks. Should this new “emergency use” authority also apply to devices subject to premarket clearance?

Response: As mentioned above, the Administration proposal prohibits devices that are reviewed through FDA's 510(k) review process from being considered for use in emergencies. Most diagnostic tests are reviewed through FDA's 510(k) process. It is not unusual for diagnostic tests that have already been approved to detect a specific bacterium or viral agent to be modified to detect another bacterium or virus of the same family. Thus, it is conceivable that a previously approved diagnostic test may also prove to be useful in screening some bioterrorist agents. FDA's 510(k) process recognizes that diagnostic test development is an iterative process that builds on the knowledge gained from the previous infectious agent to develop tests for similar agents.

AdvaMed strongly recommends that the legislation be drafted broadly to include medical devices, including 510(k) products, in all aspects of the BioShield program. The Secretaries of HHS and of Homeland Security should have the discretionary authority to consider all medical technologies, including devices, in determining what may be needed or most useful in protecting our nation from potential bioterrorist events. Devices (including devices approved through the 510(k) process) that have needed countermeasure applications, should not be excluded from consideration due to a technicality.

Question 5. Do you believe that liability protection for manufacturers is necessary in order for Project BioShield to work?

Response: It is important to understand that the countermeasure to a severe bioterrorist threat may have some severe side effects. As a result, companies that provide countermeasures to the government could be exceedingly vulnerable to liability claims. Device companies are extremely interested in partnering with the federal government but not if the potential for liability threatens the financial viability of the company itself.

Presumably, those products that are declared qualified countermeasures under Project BioShield would also be declared qualified anti-terrorism technologies under Section 861 of the Homeland Security Act and would thus be eligible for the liability protections of that Act. However, it is not clear that companies whose products are declared for use in national, public health or military emergency situations would be eligible for the Section 861 protections. Such products, by definition, have not yet been reviewed or approved for use by FDA.

Liability concerns will be a key consideration for companies manufacturing both qualified countermeasures and emergency-use products and the legislation should make clear that the liability protections of Sec. 861 of the Homeland Security Act apply to such products. For these reasons, AdvaMed urges the inclusion of strong liability protections for all aspects of Project BioShield, including medical devices.

QUESTIONS FROM CONGRESSMAN CAMP

Question 1. Two major issues in countermeasure technology development are economic incentives and liability concerns. In Secretary Thompson's testimony, he mentioned that grants and contracts might not be sufficient for developing the public/private partnership. How will Project BioShield address these issues in order to expedite the development of the next generation of countermeasures?

Response: The Administration's BioShield proposal does not appear to provide any liability protection at all to companies who are willing to partner with the federal government in developing countermeasures. As mentioned previously, a countermeasure to a severe bioterrorist threat may have some severe side effects. As a result, companies that provide countermeasures to the government could be exceedingly vulnerable to liability claims. Device companies are extremely interested in partnering with the federal government but not if the potential for liability threatens the financial viability of the company itself.

AdvaMed believes that liability concerns will be a key consideration for companies manufacturing both qualified countermeasures and emergency-use products. For these reasons, the legislation should make clear that the liability protections of Sec.

861 of the Homeland Security Act apply to all medical technologies, including medical devices.

With respect to incentives designed to encourage companies to research, develop and manufacture potential countermeasures, the greatest challenges will occur for those countermeasure technologies that have no commercial market. It can take substantial sums of money to research and develop a technology, develop supporting clinical data, conduct any needed clinical trials, construct manufacturing facilities, apply for FDA review and approval and have all the necessary infrastructure in place to comply with regulatory requirements. Before making such investments, companies do careful analysis to ensure that they will not suffer significant financial losses.

Because of the suspected nature of bioterrorism events—rare, one-time events that will likely affect only a small portion of the population at any one time—it is hard to imagine that a company would be able to fully recoup its investment, unless the product also has a commercial market. The BioShield proposal is designed to meet this challenge by allowing the Secretaries of HHS and Homeland Security, with approval from the President, to negotiate contracts with companies that will presumably enable companies to appropriately recoup their research, development and manufacturing investments.

Unfortunately, the Administration proposal explicitly excludes devices from being considered as qualified countermeasures for procurement. The proposal, as initially drafted, creates the paradoxical situation in which a device company is eligible to procure research and development funding from the NIAID to develop countermeasures with no potential commercial market. However, these same companies would be prevented from recouping their full research and development investment because the Administration proposal prevents medical devices from being purchased as a qualified countermeasure.

AdvaMed strongly recommends that the legislation be drafted broadly to include medical devices, including 510(k) products, in all aspects of the BioShield program. The Secretaries of HHS and of Homeland Security should have the discretionary authority to consider all medical technologies, including devices, in determining what may be needed or most useful in protecting our nation from potential bioterrorist events. Devices (including devices approved through the 510(k) process) that have needed countermeasure applications, should not be excluded from consideration due to a technicality.

QUESTIONS FROM CONGRESSMAN BOB ETHERIDGE

Question 1. Will private sector companies still need to raise capital to fund their initial research and development efforts?

Response: Yes. While some technologies exist that can be used or adapted for use as potential countermeasures, new technologies will also need to be developed to address situations and threats that did not appear as urgent and eminent before September 11th.

Unfortunately, it can take substantial sums of money to research and develop a technology, develop supporting clinical data, conduct any needed clinical trials, construct manufacturing facilities, apply for FDA review and approval and have all the necessary infrastructure in place to comply with regulatory requirements.

Developing a technology to prepare our nation against terrorist threats, however, has added complications because there is frequently no viable commercial market for the technology. Bioterrorist threats are expected to be one-time event that will affect only a small portion of the population at any one time. Without a viable market, it would be difficult to find investors to support the research, development, trials and production of the technology.

Question 2. If small companies have difficulty in raising capital to fund new research, how do we deal with this challenge?

Response: Due to the significant costs mentioned above in regards to researching, developing, and getting the technology approved for patient care, all companies do careful analysis to ensure that they will not suffer significant financial losses before investing in any product development. The difficulty in securing investors to support the research, development, trials and production of the technology is even more acute for small companies that cannot support the new development efforts through revenues raised from other products.

The BioShield proposal is designed to meet this challenge by allowing the Secretaries of HHS and Homeland Security, with approval from the President, to negotiate contracts with companies—essentially securing a market for the product that will allow the company to recoup their research, development and manufacturing investments.

The Administration proposal explicitly excludes devices from being considered as qualified countermeasures for procurement. Unfortunately, this exclusion would create the paradoxical situation in which a device company is eligible to procure research and development funding from the NIAID to develop countermeasures with no potential commercial market. However, these same companies would be prevented from recouping their full research and development investment because the Administration proposal prevents medical devices from being purchased as a qualified countermeasure.

AdvaMed strongly recommends that the legislation be drafted broadly to include medical devices, including 510(k) products, in all aspects of the BioShield program. The Secretaries of HHS and of Homeland Security should have the discretionary authority to consider all medical technologies, including devices, in determining what may be needed or most useful in protecting our nation from potential bioterrorist events. Devices (including devices approved through the 510(k) process) that have needed countermeasure applications, should not be excluded from consideration due to a technicality.

Question 3. Does the private sector believe that Project BioShield will work? Specifically, does the private sector think that the Administration's proposal addresses its needs to develop a mature market for the production of biomedical defenses? If not, why not?

Response: AdvaMed strongly supports the Project BioShield initiative. Specifically, AdvaMed's Council supports provisions in Project BioShield that will:

- Speed research and development on biomedical countermeasures by streamlining current NIH processes and providing funding for the construction and improvement of facilities needed to safely support research and development of countermeasures;
- Provide necessary funding to purchase biomedical countermeasures for the stockpile, particularly those countermeasures determined not to have commercial markets; and
- Allow the Secretary to make promising treatments available in an emergency, even for those products that do not yet have full FDA approval.

AdvaMed has concerns, however, that the Administration proposal explicitly excludes devices from being considered as qualified countermeasures for procurement and excludes devices approved through the 510(k) review process from being considered for emergency uses. Unfortunately, this exclusion would create the paradoxical situation in which a device company is eligible for research and development funding from the NIAID to develop countermeasures with no potential commercial market. However, these same companies would be prevented from recouping their full research and development investment because the Administration proposal prevents medical devices from being purchased as a qualified countermeasure.

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QUESTIONS FROM CONGRESSMAN TOWNS

Question 1. Given that devices, biologics and drugs usually have different standards on what makes a product commercially viable to make a commitment to R&D, does the BioShield proposal offer enough incentive for your individual industries?

Response: AdvaMed is committed to the public-private partnership for preparedness as are our member companies. AdvaMed sponsored a February 6 preparedness conference entitled "Innovation for Preparedness: the Public-Private Partnership," to strengthen the partnership between the government and the private sector on preparedness and to connect medical technology innovators with appropriate federal preparedness entities. The conference was sold out which we believe speaks volumes about the interest of the device industry in working with the government to achieve our mutual goal of defending the homeland and providing the best medical care possible.

The greatest challenges will occur for those countermeasure technologies that have no commercial market. It can take substantial sums of money to research and develop a technology, develop supporting clinical data, conduct any needed clinical trials, construct manufacturing facilities, apply for FDA review and approval and have all the necessary infrastructure in place to comply with regulatory require-

ments. Before making such investments, companies do careful analysis to ensure that they will not suffer significant financial losses.

Because of the suspected nature of bioterrorism events—rare, one-time events that will likely affect only a small portion of the population at any one time—it is hard to imagine that a company would be able to fully recoup its investment, unless the product also has a commercial market. The BioShield proposal is designed to meet this challenge by allowing the Secretaries of HHS and Homeland Security, with approval from the President, to negotiate contracts with companies that will presumably enable companies to appropriately recoup their research, development and manufacturing investments.

Unfortunately, the Administration proposal explicitly excludes devices from being considered as qualified countermeasures for procurement and excludes devices approved through the 510(k) review process from being considered for emergency uses. AdvaMed strongly recommends that the legislation be drafted broadly to include medical devices, including 510(k) products, in all aspects of the BioShield program. The Secretaries of HHS and of Homeland Security should have the discretionary authority to consider all medical technologies, including devices, in determining what may be needed or most useful in protecting our nation from potential bioterrorist events. Devices (including devices approved through the 510(k) process) that have needed countermeasure applications, should not be excluded from consideration due to a technicality.

Question 2. Do we need to add anything to this proposal to make it easier for academic research institutions and companies to work together on developing these countermeasure products?

Response: AdvaMed and its member companies have a rich history of working with academic research institutions and medical colleges in the research, development and clinical trials for many medical technologies. In November 2001, Roche Diagnostics and the Mayo Clinic announced the development of a new rapid anthrax test that can detect anthrax in humans in an hour and quickly made the test available to public health agencies and hospital and reference laboratories. AdvaMed and its companies are also working cooperatively with FDA and the CDC to speed development of a diagnostic test for West Nile virus.

The major concern for companies, whether they collaborate with academic research institutions or the government or not, is whether the resulting technology will be allowed for consideration as a qualified countermeasure for procurement. The Administration proposal explicitly excludes devices from this consideration, creating the paradoxical situation in which a device company is eligible to procure research and development funding from the NIAID to develop countermeasures with no potential commercial market. Without being considered for inclusion, the companies and institutions would be prevented from recouping their full research and development investment because the Administration the device could not be purchased as a qualified countermeasure.

AdvaMed strongly recommends that the legislation be drafted broadly to include medical devices, including 510(k) products, in all aspects of the BioShield program. The Secretaries of HHS and of Homeland Security should have the discretionary authority to consider all medical technologies, including devices, in determining what may be needed or most useful in protecting our nation from potential bioterrorist events. Devices (including devices approved through the 510(k) process) that have needed countermeasure applications, should not be excluded from consideration due to a technicality.

Question 3. If each of you had a product already approved to treat a given condition, what incentives exist in this proposal or what would you like to see to encourage research for a new countermeasure?

Response: AdvaMed strongly supports the Project BioShield initiative. Specifically, AdvaMed's Council supports provisions in Project BioShield that will:

- Speed research and development on biomedical countermeasures by streamlining current NIH processes and providing funding for the construction and improvement of facilities needed to safely support research and development of countermeasures;
- Provide necessary funding to purchase biomedical countermeasures for the stockpile particularly those countermeasures determined not to have commercial markets; and
- Allow the Secretary to make promising treatments available in an emergency, even for those products that do not yet have full FDA approval.

AdvaMed has concerns, however, that the Administration proposal explicitly excludes devices from being considered as qualified countermeasures for procurement and excludes devices approved through the 510(k) review process from being considered for emergency uses. Unfortunately, this exclusion would create the paradoxical

situation in which a device company is eligible to procure research and development funding from the NIAID to develop countermeasures with no potential commercial market. However, these same companies would be prevented from recouping their full research and development investment because the Administration proposal prevents medical devices from being purchased as a qualified countermeasure.

AdvaMed strongly recommends that the legislation be drafted broadly to include medical devices, including 510(k) products, in all aspects of the BioShield program. The Secretaries of HHS and of Homeland Security should have the discretionary authority to consider all medical technologies, including devices, in determining what may be needed or most useful in protecting our nation from potential bioterrorist events. Devices (including devices approved through the 510(k) process) that have needed countermeasure applications, should not be excluded from consideration due to a technicality.

Question 4. If a better product is developed after you have signed a contract with the government, should the government be forced to stockpile your product—because you already have a contract—or does the government need the flexibility to go with the better product, which may mean canceling your contract?

Response: While some technologies exist that can be used or adapted for use as potential countermeasures, brand new technologies will also need to be developed to address situations and threats that did not appear as urgent and eminent before September 11th.

Unfortunately, it can take substantial sums of money to research and develop a technology, develop supporting clinical data, conduct any needed clinical trials, construct manufacturing facilities, apply for FDA review and approval and have all the necessary infrastructure in place to comply with regulatory requirements.

Developing a technology to prepare our nation against terrorist threats has added complications because there is no viable commercial market for the technology. Bioterrorist threats are expected to be one-time events that will affect only a small portion of the population at any one time. Without a viable market, it would be difficult to find investors and raise capital to support the research, development, trials and production of the technology.

The BioShield proposal is designed to meet this challenge by allowing the Secretaries of HHS and Homeland Security, with approval from the President, to negotiate contracts with companies—essentially securing a market for the product that will allow the company to recoup their research, development and manufacturing investments.

If the Government, however, is not required to honor the contract it negotiates for the development of a product or technology needed to prepare our nation against bioterrorist threats, the intent of the proposal is completely undermined. Companies will continue to face significant problems in funding research, development, approval and manufacturing for the technology if there is not a guaranteed market for sale.

UNIVERSITY OF MICHIGAN HEALTH SYSTEM
CENTER FOR BIOLOGIC NANOTECHNOLOGY
April 25, 2003

The Honorable MICHAEL BILIRAKIS, *Chairman*
Subcommittee on Health
Committee on Energy and Commerce
Rayburn House Office Building
Washington, D.C. 20515

The Honorable JOHN B. SHADEGG, *Chairman*
Subcommittee on Emergency Preparedness & Response
Select Committee on Homeland Security
c/o Rayburn House Office Building
Washington, D.C. 20515

RE: March 27, 2003 Congressional Testimony—Project Bioshield Dear

CHAIRMAN BILIRAKIS AND SHADEGG: Attached are my answers to the questions submitted by members of your respective subcommittees related to testimonies given at the March 27 hearing “Furthering Public Health Security: Project Bio-shield.”

Thank you for the opportunity to address these timely and important questions. If I may be of further service, please do not hesitate to contact me at 734-647-2777 or by email at jbakerjr@umich.edu.

Sincerely,

JAMES R. BAKER, JR., MD
Ruth Dow Doan Professor
Chief, Division of Allergy & Clinical Immunology
Director, Center for Biologic Nanotechnology

cc: Marvin Pames, Executive Director, DRDA, U-M
 Mark Burnham, Director of Fed. Relations for Research, U-M

THE COMMITTEE ON ENERGY AND COMMERCE'S SUBCOMMITTEE ON HEALTH AND THE SELECT COMMITTEE ON HOMELAND SECURITY'S SUBCOMMITTEE ON EMERGENCY PREPAREDNESS AND RESPONSE.

Question 1. What things should we do to assure Technology Transfer our from NIH research, so that countermeasures can be rapidly produced?

Answer: It is important to begin with the premise that the Bioshield proposal should augment existing NIH programs. It is critical that these efforts do not undermine the existing NIH structure, which would slow research and "clog" the pipeline for Bioshield. With this in mind, it is appropriate to then target resources and efforts at specific needs for technology transfer rather than research, particularly related to biological weapons. To the extent that treatment options are present within research laboratories, then the market incentive, as created by the Bioshield proposal, could make it financially possible for companies to develop this research into viable treatments. However, as I mentioned in my written testimony, it is not clear that the specific proposals included in Bioshield will actually encourage companies to develop these treatments. This is especially true if the economic and liability issues are not resolved, and there remain unresolved impediments to dual use, commercial applications of a technology or therapeutic.

Regardless of the industry incentives to develop technologies or drugs, the creation of new bioterrorism deterrents will require substantial basic research at universities. While universities are supportive of this type of research, the present proposal does not clarify that fundamental, university-based research is an integral part of the program. Much of the proposal is focused on near-term solutions, which although vital, will likely not be the optimal outcome to protect our population. To achieve the degree of protection envisioned in Bioshield, substantial and on-going basic research will be necessary. Universities are nimble and can devote significant resources to this effort. However, while these efforts can be accelerated with additional funding, it is not clear that the 2 to 4 month grants proposed by the Administration could generate relevant and significant science. Instead, I would suggest that significant efforts are made to accelerate the pace of current research, through additional funding and by teaming academic, intramural governmental and industry researchers similar to successful endeavors in CREDA and SBIR mechanisms.

In short, Bioshield must specifically enhance university-based research programs regardless of industry incentives. The university-based research must focus on both short-term technology solutions and accelerated basic research. Finally, NIH should survey its existing intramural and extramural research programs to identify research proposals that offer rapid avenues for commercialization.

Question 2. What is your view of the Administration's research proposal?

Answer: The Bioshield proposal is an innovative attempt to remedy the reasons industry does not develop countermeasures for biological weapons. However, it is not clear that the timeframe and focus of the research component of the legislation will achieve its stated goal. As mentioned in my prior answer, the current legislation envisions research grants having short time frames that appear incompatible with the type of fundamental changes necessary to facility protection against bio-threats, particularly engineered agents. These short time frames will not even be technically viable for a range of needed treatments against current threats, such as a new smallpox vaccine. While Bioshield can and should support short-term goals where needs are critical, there also must be a commitment to accelerating fundamental research for longer time intervals. At the present time, much of the academic community does not understand how our institutions fit into this proposal or whether there is a commitment to a basic understanding of the problems involved in responding to bio-threat agents.

Question 3. [Camp Question] Two major issues in countermeasure technology development are economic incentives and liability concerns. In Sec. Thompson's testimony, he mentioned that grants and contracts might not be sufficient for developing

the public/private partnership. How will Project Bioshield address these issues in order to expedite the development of the next generation of countermeasures?

Answer: From an academic perspective, Bioshield could help foster partnerships between academic and commercial entities by providing the business sector a reason to engage in research that would otherwise have little commercial value. This would be enhanced if all entities had defined liability limitations, especially if non-approved or emergency use of a technology is envisioned. However, without an explicit role for fundamental research and a specific means for industry partnering to support this work, it is unlikely that new interest and ideas will be generated and transitioned to solve current and future needs. The key point is that while a few treatments may be possible in an extremely short time frames, most countermeasures will require substantially longer time frames for testing. In particular, it is likely that the short intervals for testing currently envisioned by the Bioshield proposal would raise substantial liability concerns since they are simply not compatible with human testing. Bioshield therefore needs to include a long-term research component to accelerate research in those areas of greatest need.

Question 4. [Townes 1] Given that devices, biologics and drugs usually have different standards on what makes a product commercially viable to make a commitment to R&D, does the Bioshield proposal offer enough incentive for your individual industries?

Answer: This is a complex issue. Devices, biologics and drugs all have difficult and somewhat unique approval processes. However, the problems tend to be individualized to a particular countermeasure as much as they are common to a particular group. For example, a killed virus vaccine for a particular infection might have substantial, dual use commercial value while a live virus vaccine for the same infection might never be acceptable for routine use in civilian populations regardless of its utility in military applications or for emergent care. Thus, the Bioshield legislation needs to provide specific incentives for those applications that are necessary but have little commercial value. However, the legislation needs to carefully address several problems related to the dual use of a technology or treatment. First of all, it should not limit Bioshield research to work that does not have any commercial use, nor should it prohibit the commercialization for another use of a countermeasure developed under Bioshield. This would lead to greater economic opportunity costs for industry than any incentive they could possibly obtain from Bioshield. It would also risk the potential public health benefits by forgoing the widest possible use of new medical options. If the government decides it needs a return on its investment for dual use applications, it can most readily accomplish this through contract or licensing negotiations.

Question 5. [Townes 2] Do we need to add anything to this proposal to make it easier for academic research institutions and commercial companies to work together on developing these countermeasure products?

Answer: The academic research community is not convinced that this version of the legislation really includes them. The focus is on treatments and devices extraordinarily close to commercialization—a type of work that is not usually performed in universities. While much of basic university research has potential to be commercialized, there are no incentives to assure that this happens. It is imperative that the legislation includes accelerated fundamental research, as well as specific financial incentives for companies to partner and commercialize university research. Otherwise, the government's tremendous investment in basic research will not be leveraged and may exclude the university programs, which have been the most active research component in the development of bioweapon countermeasures.

Question 6 [Townes 3] If each of you had a product already approved to treat a given condition. What incentives exist in this proposal or what would you like to see to encourage research for a new countermeasure?

Answer: Academic institutions continuously look for additional applications of our research results, and we do not generally have "products" as envisioned in this question. I would suggest that it be clear in the legislation both that we can look at existing products for potential use as a countermeasure, and that the countermeasures we develop can be developed for commercial use. From a public health standpoint, this ensures we are obtaining the greatest utility of our medical capabilities. In order to facilitate this public good, industry should be allowed to retain its intellectual property to both the existing commercial products and the commercial uses of developed countermeasures. The impact of such a commercial use on the cost of the program can and should be dealt with in the terms of the individual contract since the commercialization potential will vary widely across the possible countermeasures.

Question 7 [Townes 4] If a better product is developed after you have signed a contract with the government, should the government be forced to stockpile your

product—because you have a contract—or does the government need the flexibility to go with the better product, which may mean canceling your contract?

Answer: The committee might consider structuring these contracts in a manner similar to NASA performance-based contracts for the development of spacecraft. There, industry is generally paid for the actual costs of research and construction, often these payments are made at specific milestones. Upon completion, the contractor is then paid a performance fee which includes incentive payments and profit. If such a contract were structured, there would be no reason that the parties could not agree in the contract to allow the government to cancel the contract, paying through the next milestone (thus covering the contractor's actual costs) and then the performance payment (thus guaranteeing the company a profit without completing the production of the drug).

Question 8 [Townes 5] This bill appropriates unlimited sums of money. However, our orphan drug program also gives incentives to work on R&D for diseases that are not that prevalent, and many illnesses still have no cure. Is Bioshield a research problem that money alone can solve?

Answer: Bioshield cannot solve the problem of bioterrorism by money alone. However, a comparison to the orphan drug program is not entirely appropriate, because the urgency and scale of these issues are completely different. Money is one necessary ingredient, although no more important than collaboration among researchers of various disciplines, cooperation between academic, government and industry partners, and having adequate time to perform the work. This last requirement may be the most vexing. In order to achieve the goals of the proposal, we will need time to develop new medical responses to biological weapons. The current legislation may induce industry to develop a few treatments that may have languished in regulatory limbo, but the vast majority of treatments are simply not waiting for commercialization. Fundamental research remains to be conducted to answer many of the primary questions of how these countermeasures might function, and to provide proof of concept that a countermeasure is effective. In fact, even for those situations where there appears to be a viable treatment alternative, there are often adverse effects that provide a need for continuing research to develop better treatments. Examples of this abound, be it approaches with fewer complications (e.g. the smallpox vaccine) or to new countermeasures necessary should the potential pathogen be able to defeat our defense, (e.g. antibiotic resistant anthrax). That is why most diseases, whether covered by the orphan drug act or the Bioshield proposal, require substantial money and time for basic research to find an effective cure.

UNIVERSITY OF MICHIGAN HEALTH SYSTEM
CENTER FOR BIOLOGIC NANOTECHNOLOGY
April 25, 2003

The Honorable JOHN D. DINGELL
Subcommittee on Health
Committee on Energy and Commerce
Rayburn House Office Building
Washington, D.C. 20515

The Honorable Sherrod Brown
Subcommittee on Health
Committee on Energy and Commerce
Rayburn House Office Building
Washington, D.C. 20515

RE: March 27, 2003 Congressional Testimony—Project Bioshield

DEAR CONGRESSMAN DINGELL AND BROWN: Attached are my answers to the questions submitted by members of the subcommittees related to the March 27 hearing "Furthering Public Health Security: Project Bioshield."

Thank you for the opportunity to address these timely and important questions. If I may be of further service, please do not hesitate to contact me at 734-647-2777 or by email at jbakerjr@umich.edu.

Sincerely,

JAMES R. BAKER, JR., MD
Ruth Dow Doan Professor
Chief, Division of Allergy & Clinical Immunology
Director, Center for Biologic Nanotechnology

cc: Marvin Pames, Executive Director, DRDA, U-M
Mark Burnham, Director of Fed. Relations for Research, U-M
Eugenia Edwards, Committee on Energy and Commerce

Candace Butler, Committee on Energy and Commerce

THE COMMITTEE ON ENERGY AND COMMERCE'S SUBCOMMITTEE ON HEALTH AND THE
SELECT COMMITTEE ON HOMELAND SECURITY'S SUBCOMMITTEE ON EMERGENCY
PREPAREDNESS AND RESPONSE.

Question 1. There were some questions raised during the hearing regarding the Bayh-Dole Act and its effectiveness. Please explain how Bayh-Dole is working on your campus and throughout academia. Is it successful? How should success be measured? Is it encouraging or impeding partnership with private industry? Does it make a difference in getting research discoveries and technologies into the market?

Response. *The Economist*, in its December 12, 2002 article entitled, "Innovation's Golden Goose," said that The Bayh-Dole Act of 1980 is, "perhaps the most inspired piece of legislation to be enacted in America over the past half-century."

Giving American universities both the right and the responsibility to commercialize technologies developed with taxpayers' money, Bayh-Dole ushered in an era in which universities began to have an unprecedented impact, both technologically and economically. In the eyes of many, this landmark legislation is responsible for today's knowledge economy.

According to the article in *The Economist*, the original Bayh-Dole legislation, together with its 1984 amendments and its augmentation in 1986, "unlocked" the inventions and discoveries that had been made in university laboratories and, "helped to reverse America's precipitous slide into industrial irrelevance."

Our experience at the University of Michigan would tend to corroborate these findings. In just the past five years, as a consequence of the intellectual property rights granted by Bayh-Dole, the University of Michigan has spawned 34 start-up companies and granted 267 technology licenses to existing companies. At the University of Michigan, we have filed 590 patent applications over that same period.

Nationwide, there has been an increase in patents originating from universities. According to the Association of University Technology Managers (AUTM), "Prior to Bayh-Dole, fewer than 250 U.S. patents were issued to universities each year. Since 1993, U.S. universities participating in the Survey have averaged more than 1,600 U.S. patents annually. In recent years, patents issued to U.S. universities have exceeded 2,000."

The effect of this increase in patenting on public health should not be underestimated. These patents have lead to the development and commercialization of innumerable advances in medical diagnostics, devices and care. Why is patenting important? It provides researchers economic incentives to continue working with industry to develop laboratory research into a useable product. This is important because researchers typically would move on to the next research project without this incentive, and researcher involvement is often critical in developing a technology beyond the lab. Similarly, the intellectual property rights ensure industry that their investment in this research will inure a benefit back to the company.

Without the incentives and obligations inherent in Bayh-Dole, universities might not have stepped up to develop the technology transfer programs which made these great achievements possible, and they might not have invested in the development of a professional cadre skilled in moving ideas from academia to the marketplace. This growth is reflected in the growth of AUTM which now counts over 200 universities actively engaged in technology transfer activities, an eightfold increase in less than twenty years.

A variety of relationships with industry have continued to be an important element of university-based research and technology transfer. At the University of Michigan, our large research centers generate patents which are licensed non-exclusively to all industry affiliates within the consortium; we license some patents exclusively to large and small companies; in joint research endeavors we recognize joint inventorship and joint ownership of intellectual property. Thus, as do nearly all research universities, we have found that all kinds of arrangements can be forged with industry, whether in biotechnology, engineering, or information technology. In 2000, industry sponsored \$317 million in research at U.S. universities, hospitals and research institutes, the overwhelming portion of which was for biomedical research.

In addition to being the Ruth Dow Doan Professor at the School of Medicine; Chief, Division of Allergy; and Director, Center for Biologic Nanotechnology at the University of Michigan, I am also the Chief Science Officer of a university spinout company by the name of NanoBio Corporation. It is doubtful that NanoBio, a biopharmaceutical company that has licensed biologic nanotechnology delivery systems from the University would be in existence if not for the Bayh-Dole Act. Furthermore, it is doubtful that we could be considered for venture capital backing if not

for the provision in Bayh-Dole that allows for the exclusive licensing of federally funded research.

Question 2. It was suggested during the hearing that Bayh-Dole is enabling the drug companies, and others, to make an inordinate amount of profit based on federally-funded research without providing the government an adequate return on that investment. Is this an accurate depiction of the effect of Bayh-Dole? Should Bayh-Dole be amended to change this situation?

Response. Given the strong concern with the cost of pharmaceuticals it is entirely understandable that attention would be directed at how research universities contribute to the products manufactured and marketed by large corporations. However, these questions are premised on the false assumptions that the federally sponsored research provides the pharmaceutical industry a free ride on the costs of research, and that we could lower the costs of drugs if only the federal government didn't allow universities to retain intellectual property rights under Bayh-Dole. In truth, many drugs would not be developed at all if not for the technology transfer incentives established by Bayh-Dole, and the pharmaceutical industry is not getting a free ride. It costs \$600 million and takes on average 11.2 years from the time a new drug is discovered until it is approved by the Food and Drug Administration. Licenses to the pharmaceutical industry are but a small part of the drug discovery and approval process, and the vast majority of licenses yield little income to universities.

To properly understand this issue, it is imperative that we understand why Bayh-Dole even exists. In the late 1970s and 1980s, approximately 80% of basic research was funded by the federal government, which then retained title to the intellectual property generated by that research. During this time, there were few, if any new drugs commercialized based upon federally funded basic research. Recognizing that universities were not in a position to work with industry to commercialize the results of their research, absent some ownership of the intellectual property, and realizing that the vast majority of federally owned intellectual property was sitting on the shelf unused, Congress decided to create an incentive for federally funded researchers to take the portion of their research which lends itself to commercialization—and commercialize it. By enabling the university to retain title to the intellectual property, and then mandating that the university disclose the invention and attempt to commercialize it, Congress unleashed one of the most significant technology development and economic engines in our economy.

I must also note that universities do not generally make a profit on this activity. Technology transfer is time consuming and costly; most universities are doing well if the revenue from their intellectual property pays for the technology transfer operations. Also, to the extent that a university does make any money from its licenses, Bayh-Dole mandates that those funds be spent on education and scientific research. Technology transfer is therefore consistent with our mission of gathering knowledge and diffusing it for the benefit of society. It is not about making money; if we generate returns, we use those funds to further our missions of education and research.

So is it worth it, does it work? Absolutely, the economic and social impact of Bayh-Dole has been very significant. Industry and academia are teaming up more than ever before, and the results are new companies, new products, improved public health and a higher quality of health care and life. Universities play a key role in the discovery of some new medical treatments, devices and other countermeasures critical to homeland security.

Is the government getting a return on its investment? Absolutely. Thousands of jobs are created, generating salaries and corporate income that are then taxed by federal and state government. Technology developed through federal assistance is being transferred, to the benefit of society. Returning to government ownership, or some sort of public domain ownership of university intellectual property would not only hinder our nation's capabilities to bring the results of research into the marketplace, it could result in fewer new products, less industry research and poorer public health.

Although I appreciate that the high cost of drugs is a significant concern, dismantling the Bayh-Dole system will not only fail to accomplish the goal of lower drug prices, but will effectively undermine much of our economy. As both the NIH and PCAST have said in recent studies of Bayh-Dole, Bayh-Dole is working well, and should be left alone.

To try and "tax" Bayh-Dole would seriously limit its effectiveness. Less than 1 in 100 licensees ever make a substantial profit from their work. An up-front fee or obligation would provide a serious disincentive to commercialization that would likely limit the academic commercial incentives that the current legislation is attempting to foster. If there are concerns about profits on the few drugs that make commercial success, it would make much more sense to tax the profits of these companies. This

would provide the most significant recoup on the research investment of Bayh-Dole and would not directly hamper commercial development.

As it relates to Bioshield, the ultimate cost of the research, development and production of new countermeasures will necessarily be a critical issue for how the contracts will be structured. Since Bayh-Dole already provides the federal government with both no cost, non-exclusive licenses and "march in" rights for every patent generated under Bayh-Dole, repealing or modifying Bayh-Dole will not improve the government's negotiating position on these contracts and will have no bearing on the ultimate cost of these countermeasures. Considering the important role Bayh-Dole plays in the development of new technologies, any attempt to repeal or amend it should be opposed.

May 5, 2003

The Honorable MICHAEL BILIRAKIS, *Chairman*
Subcommittee on Health
U.S. House of Representatives
Committee on Energy and Commerce
Rayburn House Office Building
Room 2125
Washington, DC 20515-6115

The Honorable JOHN B. SHADEGG, *Chairman*
Subcommittee on Emergency Preparedness and Response
Select Committee on Homeland Security
2402 Rayburn House Office Building
Washington, DC 20515

Re: Response to Questions for the Record of the Hearing on "Furthering Public Health Security: Project Bioshield" (March 27, 2003)

DEAR CHAIRMAN BILIRAKIS AND CHAIRMAN SHADEGG: I have enclosed my responses to the follow-up questions enclosed in your letter to me dated April 9, 2003.

Best regards,
 Sincerely,

MICHAEL A. FRIEDMAN

RESPONSES TO THE HONORABLE MICHAEL BILIRAKIS

Question 1. What are the main scientific challenges facing companies involved in bioterrorism countermeasure research?

Response: Bringing a drug from concept to market takes 10 to 15 years, which reflects the greater complexity of target diseases, the longer and larger clinical trials now required by FDA, and the medical system's demand for more complex data about new drugs. As a result, the average cost to develop a new drug has grown from \$138 million in 1975 to \$802 million in 2000. The risks involved in the new drug development and approval processes are also substantial. For every 5000 compounds screened, 250 drugs enter preclinical testing, and of every 250 drugs that enter preclinical testing, only 1 is approved by FDA. Research and development of bioterrorism countermeasures presents significant additional scientific challenges. First, handling highly dangerous pathogens is expensive and time-intensive. Second, a limited number of experts and facilities are available for research and development involving biothreat agents. To work on most biothreat agents, a laboratory must be constructed at the highest bio-safety level (bio-level 4 or "BL4"). There are only four BL4 labs in the United States, and three are owned by the U.S. Government. Third, because so few scientists have worked with biothreat agents, the development and production of a countermeasure could require tapping into scientific expertise from a broad spectrum of the individuals in the pharmaceutical and biotechnology industry, government, and the academia. Fourth, traditional clinical effectiveness trials using human subjects are neither ethical nor lawful. For each countermeasure agent, a relevant animal model must be developed, a process which can be time-consuming and expensive.

Question 2. In discussing the need for more bioterrorism countermeasures, much of the focus has been on vaccines. What types of countermeasures can be pursued by traditional "large molecule" drug companies?

Response: The companies with experience researching, developing, securing approval for, and marketing drug products and biological products—whether vaccines or therapeutics, whether small-molecule or large-molecule—are essential to the effort to build an effective U.S. armamentarium against biological weapons. Some im-

portant countermeasures—including antibacterials (antibiotics), antifungals, antivirals, and immune enhancers—will be large molecule products. Also, as the Director of NIH pointed out at the hearing on March 27, research into emerging and re-emerging infectious diseases will inform and benefit biodefense research.

Question 3. What type of countermeasure work is being done by PhRMA companies in conjunction with NIH and other Federal agencies?

Response: As indicated in my written statement, PhRMA and its member companies are working closely with the NIH and other federal agencies to move forward with countermeasure research. For example, PhRMA is working with NIH, CDC, DoD, FDA, and academia to support *in vitro* studies of five pathogens (*B. anthracis*, *Y. pestis*, *Brucella* spp., *F. tularensis*, and *Burkholderia* spp.) for testing of existing antibiotics. Several companies are working with NIAID, DoD, and FDA to test existing antibiotics against plague. Several have offered to have existing drugs tested against additional biothreats.

Question 4. Should liability protections be included in any BioShield proposal considered by Congress?

Response: Any Bioshield legislation should include liability protection for companies that enter into contracts for the research and development or the procurement of countermeasures and for all parties involved in the manufacture, distribution, and administration of products under the special emergency authorization provisions. PhRMA hopes to work with the Administration and Congress to ensure the legislation includes appropriate product liability protection along the lines of the swine flu model or Section 304 of the Homeland Security Act. Neither indemnification under Public Law 85-804 (which would cover only products subject to procurement contracts) nor the narrow “government contractor defense” available in some situations under Subchapter G of the Homeland Security Act would be adequate to assure pharmaceutical companies that the risks inherent in the research, development, and manufacture of countermeasures can be adequately managed.

Question 5. Under Project BioShield, before the Secretary can decide to purchase a countermeasure, he must first determine that there is otherwise “no significant commercial market.” What types of factors should guide the Secretary in making this determination?

Question 6. Should the BioShield procurement authorities apply only to new drugs? That is, isn’t the fact that a drug is currently on the market evidence that a “significant commercial market” for the drug exists?

Response: PhRMA opposes the inclusion of a “no significant commercial market” requirement. This would apparently preclude procurement of antibiotics and broad-spectrum antivirals. It might also discourage companies from further testing of antibiotics and antivirals currently on the market. Further, it might discourage companies from including countermeasure research in existing anti-infective research and development programs. Research into emerging and re-emerging diseases could provide vital information for biodefense research. For example, at a recent medical conference in Prague, it was reported that very preliminary research has shown that a derivative of the HIV anti-viral drug cidofovir might help combat smallpox. Any legislation passed should ensure that BioShield funds may be used to purchase antibiotics and anti-virals with dual-use potential.

Question 7. Project BioShield also allows the Secretary to use unapproved drugs during emergencies, but only if the benefits of the drug outweigh the risks, and there is no available alternative. In an emergency, should the Secretary be able to authorize the use of an unapproved drug, when there might be an alternative, but the alternative is more dangerous?

Response: The Senate Bill provides that the Secretary may issue an authorization if he concludes: (1) the agent specified in the determination can cause a serious or life-threatening disease or condition; (2) based on the totality of scientific evidence available to the Secretary (including data from adequate and well-controlled clinical trials, if available), it is reasonable to believe that the product may be effective in detecting, diagnosing, treating, or preventing the disease or condition (or a serious or life-threatening condition caused by a product authorized under section 564 or approved for detecting, diagnosing, treating, or preventing that disease or condition); (3) the known and potential benefits of the product, when used for this purpose, outweigh its known and potential risks; (4) there is no adequate alternative to the product that is approved and available; and (5) any other criteria prescribed in regulation are met. Patient safety remains the research-based industry’s highest priority. We believe the hypothetical presented in the question can be addressed with the current language, provided the Secretary has the discretion to determine whether an approved alternative is “adequate.”

Question 8. Do you believe that the Secretary should have the ability to limit off-label uses of drugs authorized for emergency use?

Response: A legislative prohibition of off-label use would be unprecedented. It would effectively require FDA to regulate the practice of medicine, something that it has stated for decades it does not do.

RESPONSES TO THE HONORABLE BOB ETHERIDGE

Question 9. Will private sector companies still need to raise capital to fund their initial research and development efforts?

Question 10. If small companies have difficulty in raising capital to fund new research, how do we deal with this challenge?

Response: In order to undertake research and development into countermeasures, a company will need to reallocate resources and personnel from research relating to other diseases and conditions, raise new funds to be earmarked specifically for countermeasure research and development, or both. The decision to divert resources and personnel from the research and development of medicines for serious illnesses like heart disease can be financially risky, especially for a company with few products on the market or in the pipeline. (This diversion of resources and personnel will also affect the future availability of treatments and cures for patients with other serious health conditions—especially since fewer than ten percent of all drugs that enter testing ever demonstrate sufficient safety and acceptable efficacy.) Raising new capital is likewise a difficult and potentially risky undertaking. In light of the legal, economic, and scientific challenges inherent in this undertaking, any legislation implementing Project BioShield should include appropriate liability protection and a contracting and procurement process tailored to this special context.

Question 11. What patent rights will companies enjoy under Project Bioshield? If companies are concerned that their patents might be challenged, how do we deal with this fear?

Response: We do not understand Project Bioshield to make any changes to intellectual property protection currently available under U.S. law. Granting patents is one of the primary ways in which governments create incentives for making the investment in new innovations. A patent gives an inventor the right to prevent others from making, using, and selling an invention for a limited period of time. Patents provide the opportunity to recoup the time and money invested in innovation. They are critical to research-intensive industries such as the pharmaceutical industry, for which R&D represents the major cost of bringing a product to market.

Question 12. Does the private sector believe that Project Bioshield will work? Specifically, does the private sector think that the Administration's proposal addresses its needs to develop a mature market for the production of biomedical defenses? If not, why not?

Response: Project Bioshield is an important first step towards development of a complete armamentarium of vaccines, diagnostics, and therapeutics to counter biological and chemical weapons. There are, however, many scientific, legal, and economic challenges inherent in the research and development of these countermeasures. These challenges can be addressed, in part, with the inclusion of adequate liability protection and with provisions that tailor the contracting and procurement process to better fit the R&D model of the pharmaceutical and biotechnology industry. We look forward to working with the Administration and Congress to ensure that legislation adequately addresses these issues.

RESPONSE TO THE HONORABLE DAVE CAMP

Question 13. Two major issues in countermeasure technology development are economic incentives and liability concerns. In Secretary Thompson's testimony, he mentioned that grants and contracts might not be sufficient for developing the public/private partnership. How will Project Bioshield address these issues in order to expedite development of the next generations of countermeasures?

Response: Any Bioshield legislation should include liability protection for companies that enter into contracts for the research and development or procurement of countermeasures and for all parties involved in the manufacture, distribution, and administration of products under the special emergency authorization provisions. PhRMA hopes to work with the Administration and Congress to ensure the legislation includes appropriate product liability protection along the lines of the swine flu model or Section 304 of the Homeland Security Act. Neither indemnification under Public Law 85-804 (which would cover only products subject to procurement contracts) nor the narrow "government contractor defense" available in some situations under Subchapter G of the Homeland Security Act would be adequate to assure pharmaceutical companies that the risks inherent in the research, development, and manufacture of countermeasures can be adequately managed.

The Department of Defense (DoD) and the Defense Advanced Research Projects Agency (DARPA) have the power to enter into research and development or prototyping arrangements under what is known as "Other Transactions Authority." This authority can provide much more flexibility than is typically the case under federal acquisition regulations and can be used to develop agreements that more closely resemble commercial transactions. It also has been used to encourage and provide for the establishment of industry teams in federal contracting. In any legislation implementing Project Bioshield, the Secretary of Health and Human Services should be granted OTA for the purpose of securing both R&D and actual countermeasures.

RESPONSES TO THE HONORABLE GENE GREEN

Question 14. Dr. Baker alleges that the incentives in the Bioshield initiative are not large enough to attract the bigger companies, and we will have to rely more on smaller start up companies who are more willing to take risks. Do you agree with his assessment on this issue? What work is currently being done at some of your member companies to combat bioterrorism?

Response: PhRMA does not have a complete list of the relevant research currently underway at its member companies. As indicated on PhRMA's website, however, a 2002 survey of medicines in development for infectious diseases found that pharmaceutical and biotechnology companies were working on 256 medicines for infectious diseases, including medicines for smallpox, anthrax and plague. A cooperative and collaborative research and development effort, which engages both the smaller and larger biotechnology and pharmaceutical companies, as well as government and academia, will be essential to ensuring the timely research, development, and production of bioterrorism countermeasures. In order to foster this effort, any legislation implementing Project BioShield should include effective liability protection; modifications to the ordinary government contracting and procurement process in order to better fit the research and development model of the pharmaceutical and biotechnology industry; and narrow provisions granting relief from antitrust constraints in order to permit certain types of meetings under certain circumstances.

Question 15. Some of us have been grilling PhRMA witnesses for some time to try to get a better sense of exactly how much it costs to develop a drug, and while we've never gotten a straight answer, but it is safe to assume that it costs millions of dollars and takes many years. Is the timeframe in this legislation realistic? I just wonder whether throwing a lot of money at the industry will yield results any faster?

Response: The average cost to develop a new drug has grown from \$138 million in 1975 to \$802 million in 2000. Bringing a drug from concept to market takes 10 to 15 years. Under the President's Project Bioshield legislation, in order to enter into a procurement contract for a countermeasure, the Secretary of HHS must determine that production and delivery of the product within five years is reasonably expected to be feasible. The five-year condition may operate to preclude the Secretary from entering into contracts for promising research, in light of the length of the new drug research and development process. We recommend deletion of this requirement.

Question 16. The PhRMA website states that "a 2002 survey of medicines in development for infectious diseases found that pharmaceutical and biotechnology companies were working on 256 medicines for these diseases, including medicines for smallpox, anthrax and plague." If the industry is already taking steps to develop countermeasures for these products, is there a need for this type of legislation?

Response: PhRMA companies are engaged in research and development relating to a large number of infectious diseases. Some research is being done on medicines for smallpox, anthrax, and plague. It is generally recognized, however, that the U.S. needs a full arsenal of vaccines, diagnostics, and therapeutic products for a much wider range of biothreat agents. For many companies, however, there are significant disincentives to the research and development of bioterrorism countermeasures. These disincentives include the expense and time involved in developing a new product that, even if successfully developed by the company and then approved by FDA, may never be sold, or—if sold—may be sold only to one purchaser (e.g., DoD) that makes no commitment to long-term purchase. Liability exposure can be significant and unavoidable, and private insurance can be prohibitively expensive or unavailable. Opportunity costs, when resources are diverted from the research and development of other medicines, can be prohibitive, particularly for companies with pipeline products only in very early stages of development. The need for rapid development of countermeasures also may require a level of collaboration among companies and with the government that raises antitrust concerns. Project Bioshield is an important first step towards creating an infrastructure that fosters the research

needed. For the reasons outlined in this paragraph, however, any legislation implementing Project BioShield should include liability protection, modifications to the ordinary government contracting and procurement process in order to better fit the research and development model of the pharmaceutical and biotechnology industry, and narrow provisions granting relief from antitrust constraints in order to permit certain types of meetings under certain circumstances.

RESPONSES TO THE HONORABLE EDOLPHUS TOWNS

Question 17. Given that devices, biologics, and drugs usually have different standards on what makes a product commercially viable to make a commitment to R&D, does the Bioshield proposal offer enough incentive for your individual industries?

Response: Project Bioshield is an important first step towards creation of complete armamentarium of vaccines, diagnostics, and therapeutics to counter biological and chemical weapons. There are, however, many scientific, legal, and economic challenges inherent in the research and development of these countermeasures, all of which function as disincentives. These challenges can be addressed, in part, with the inclusion of adequate liability protection and provisions that tailor the contracting and procurement process to better fit the research and development model of the pharmaceutical and biotechnology industry. We look forward to working with the Administration and Congress to ensure that the legislation adequately addresses these issues.

Question 18. Do we need to add anything to this proposal to make it easier for academic research institutions and commercial companies to work together on developing these countermeasure products?

Response: A cooperative and collaborative research and development effort, which engages both the smaller and larger biotechnology and pharmaceutical companies, as well as government and academia, is essential to ensuring the timely research, development, and production of bioterrorism countermeasures. The President's Bioshield legislation is an important step in this process. My written testimony described ways in which PhRMA member companies are already collaborating with academia and government to begin this research. There are, however, many scientific, legal, and economic challenges inherent in the research and development of these countermeasures. These challenges can be addressed, in part, with the inclusion of adequate liability protection, provisions that tailor the contracting and procurement process to better fit the R&D model of the pharmaceutical and biotechnology industry, and narrow relief from antitrust constraints for certain meetings provided safeguards are in place.

Question 19. If each of you had a product already approved to treat a given condition, what incentives exist in this proposal or what would you like to see to encourage research for a new countermeasure?

Response: While Project Bioshield is an important first step towards development of a comprehensive arsenal of vaccines, diagnostics, and therapeutics to combat bioterrorism, there are many scientific, legal, and economic challenges inherent in the research and development of these countermeasures. These challenges can be addressed, in part, with the inclusion of adequate liability protection, provisions that tailor the contracting and procurement process to better fit the R&D model of the pharmaceutical and biotechnology industry, and narrow relief from antitrust constraints for certain meetings provided safeguards are in place. These can be more accurately characterized as removing disincentives to research, rather than incentives. Of course, PhRMA itself does not conduct product research or development. While Project Bioshield does not contemplate incentives, any individual company contemplating countermeasure research and development may find a particular incentive or other provision especially important in view of its own research capabilities, portfolio, and pipeline.

Question 20. If a better product is developed after you have signed a contract with the government, should the government be forced to stockpile your product—because you already have a contract—or does the government need the flexibility to go with the better product, which may mean canceling your contract?

Response: The pharmaceutical research and development model is not like the research and development model of ordinary government contractors. It is uniquely time consuming, costly, and risky. Other factors in this special context—including high liability exposure and the challenge of reallocating resources (i.e., diverting funds and scientists from research into other diseases and conditions)—will amplify the risks and serve as significant disincentives to countermeasure R&D by private industry. Legislation intended to encourage research and development into countermeasures should not allow the government to terminate its contracts when additional products are developed. The uncertainty associated with this termination au-

thority would operate as a significant disincentive to research and development of countermeasures. At the same time, competition is essential to innovation, and any legislation passed should encourage pharmaceutical and biotechnology companies to compete by developing and manufacturing newer and better versions of already-procured products. The pharmaceutical industry looks forward to working with the Administration and the Congress to develop a contracting and procurement model that would mimic the “real market” and encourage private sector competition.

Question 21. This bill appropriates unlimited sums of money. However, our Orphan Drug program also gives incentives to work on R&D for diseases that are not that prevalent, and many illnesses still have no cure. Is BioShield a research problem that money alone can solve?

Response: Project Bioshield is an important first step. As I indicated in my testimony on March 27, the President's proposal speaks primarily to the early and the late steps in the lengthy, high-risk, and costly process of bringing new medicines to the market. It does not speak to the time consuming and resource intensive middle part of that process, which is largely our responsibility. There are many scientific, legal, and economic challenges inherent in this part of the process. These challenges can be addressed, in part, with the inclusion of adequate liability protection, provisions that tailor the contracting and procurement process to better fit the R&D model of the pharmaceutical and biotechnology industries, and narrow relief from antitrust constraints to permit certain types of meetings, with government officials present and appropriate safeguards in place.

RESPONSES FOR THE RECORD SUBMITTED BY HON. TOMMY THOMPSON

Questions are numbered sequentially 1-38. Questions were submitted as follows: Chairman Tauzin, questions 1-6; Chairman Shadegg; #7; Mr. Turner #8; Mr. Weldon #9; Ms. Wilson #10; #11 [unspecified]; Ms. Lowey #12-17; Mr. Green #18-22; Mr. Lincoln Diaz-Balart #23-24; Mr. DeFazio #25-28; Mr. Camp #29; Chairman Bilirakis #30-31; Mr. Etheridge #32; Mr. Bennie Thompson #33-38.

QUESTIONS AND ANSWERS:

Question 1: To qualify for procurement under Project BioShield, the government must first determine that there is “no significant commercial market” for the countermeasure. Who would make this decision? What criteria would guide the decision maker?

Response: The bill states that the HHS Secretary shall make this determination. See sec. 121(c)(3)(B)(iii), as added by section 3 of the bill.

The Secretary would likely be guided in making this determination by the Federal Acquisition Regulations (FAR). The FAR sets forth guidance for determining whether a particular product or service is a “commercial” product or service. Specifically, FAR 2.101 supplies an in-depth definition of the term “Commercial item.” Factors which would result in classifying a product as commercial include: (1) if the item is customarily used by the general public or by non-governmental entities for purposes other than governmental purposes, (2) if the item is sold or leased to the general public, and (3) if the item has been offered for sale, lease, or license to the general public. Contracting officers are accustomed to using market research and market surveys to determine whether these factors exist, and the Department would be able to use these methods to make the “no significant commercial market” determination under the bill.

Question 2: Is the fact that a product has already been approved conclusive evidence that there is a “significant commercial market” for the product? In other words, will Project BioShield only apply to new drugs and vaccines?

Response: No, approval for a product is not conclusive evidence that there is such a commercial market. In fact, the definition of “qualified countermeasure” in the Countermeasures Procurement section of the bill is drafted to explicitly preserve the possibility of using this authority to procure products that have been approved or licensed.

Question 3: Are medical devices eligible for purchase by the government under Project BioShield? If not, why not?

Response: Under the Administration's bill, the Countermeasures Procurement section would provide authority for procuring drugs and biological products, but not devices. This section would provide extraordinary spending authority to spur the private sector to invest in next-generation countermeasures against biological, chemical, radiological, and nuclear weapons. The Administration plans to continue to develop and acquire new devices to diagnose and respond to threats under current funding authorities. The Government could purchase devices for the Strategic Na-

tional Stockpile, but it would do so using existing authority and annual appropriations rather than the special fund to be created by the Project BioShield bill.

Question 4: Regarding the “emergency use” authority in Project BioShield, could the government authorize the use of a clearly superior, yet unapproved countermeasure if another inferior (in terms of risk profile or efficiency, for example) countermeasure was approved and available?

Response: Yes. Under the bill, one of the conditions for granting emergency use authorization is that “there is no adequate, approved, and available alternative” to the product. If another product was approved and available, an unapproved product could still be given emergency use authorization if it was determined that the approved product was not adequate for that indication.

Question 5: Can you outline what the Administration has done, and will continue to do, regarding securing private sector advice in the creation of a countermeasure’s development effort, and what has private industry told the Administration regarding its requirements particularly related to guaranteed procurement?

Response: Dr. Fauci and other HHS officials consulted with the private sector as the Project BioShield proposal was being developed and continue this dialogue. The industry has indicated that the absence of a secure and predictable funding source discourages them from investing in the technology and infrastructure needed to develop cutting edge biomedical products where the Government is the only market. When the private sector considers developing a new product, the first thing it does is assess the potential market for the product. Biomedical countermeasures, like vaccines against Anthrax or Ebola, have only one market: the Government. If there is not a secure funding source behind this market, there is little reason for a biotech or pharmaceutical firm to invest in products responsive to this market. From their point of view, it makes more sense to invest in a next generation cholesterol lowering therapy or some other blockbuster drug. The current state of the country’s countermeasure armamentarium confirms this assessment. Very little in the way of innovation has occurred over the last few decades for countermeasures against the Category A agents (smallpox, anthrax, tularemia, plague, botulinum toxin and the viral hemorrhagic fevers). While Dr. Fauci and his colleagues at NIH have made substantial progress on a vaccine against Ebola, the smallpox vaccine has changed only modestly over the last 100 years and the current generation anthrax vaccine was developed in the 1960s. Luckily, anthrax, plague, and tularemia respond to antibiotics that were developed for other conditions. It seems clear the uncertainty inherent in the annual appropriations process has played a large role in discouraging innovation in countermeasures against Category A agents and for other countermeasures where the Government is the only likely purchaser.

Question 6: The Administration’s BioShield proposal includes the concept of “emergency use” authorization that would allow for “contingent FDA approval” of countermeasures. Can you explain how this would be done, how long would the “contingent approval” last, and under what circumstances would this “contingent approval” be revoked? How would a revocation impact the liability of a private company product given an “emergency use” authorization?

Response: Emergency use authorization would not be a contingent FDA approval. It would be an emergency authorization to use an unapproved product or to use an approved product for an unauthorized use in an emergency to respond to a serious public health threat. To invoke this authority:

- The Secretary of Homeland Security, the Secretary of Defense, or the Secretary of HHS, as appropriate, would have to determine that there is an emergency involving a particular biological, chemical, radiological, or nuclear agent, or a specific disease.
- In response to such a determination, the Secretary of HHS may authorize the use of a drug, biological product, or device in an actual or potential emergency.
- The Secretary may impose conditions on the use of products authorized in this manner. These conditions may relate to product labeling, distribution, who may administer the product and under what circumstances it may be administered, the performance of studies, trials or research related to the product, record-keeping, good manufacturing practices, and the monitoring and reporting of adverse events.

The authorization would last until the termination of the emergency declared by the Secretary (at most one year, unless renewed), or until the Secretary revoked the authorization.

The Secretary may revoke an authorization if, in the Secretary’s judgment, the conditions for the authorization are no longer met or other circumstances make revocation appropriate.

A manufacturer’s liability (e.g., for alleged product defects) should not be directly affected either by the granting of an authorization or by the revoking of one.

Question 7: Mr. Secretary, the Defense Science Board in its May 2002 Study on Defense Science and Technology has issued a challenge to DoD that by 2005, the pathogen to drug hit process should be reduced from years to months, by 2010 from months to weeks, and by 2020, it should have the ability to go from bug to drug within 24 hours. It has recommended spending \$200 million per year over the next twenty years to achieve this. What do you think of the likelihood of their success? Are they on target in terms of the financial commitments? What sort of communication/collaboration do you have with the Department of Defense in terms of R&D of countermeasures? What is your opinion of the Defense Science Board's challenge on going from bug to drug within 24 hours by 2020?

Response: The Defense Science Board's (DSB's) challenge and recommendations are at once inspiring and formidable. There is cause for optimism, however. For example, HHS is seeing a steady stream of scientific and medical progress flowing from the revolution in genomics and proteomics. In this regard, an ongoing, concerted, multi-agency federal program to sequence the genomes of Categories A, B, and C pathogens is crucial. It has been possible to greatly accelerate this effort with recent increases in biodefense funding at the NIH. Furthermore, evidence of the realism of the Board's time frame is suggested by the incredibly rapid identification and molecular dissection of the causative agent of SARS, and the program, almost completed, to screen currently available antiviral drugs for anti-SARS activity. However, one should not underestimate the challenge posed by the DSB, and it remains to be seen whether it can be met within the specified timeframe. It is clear, however, that HHS efforts in biodefense research are compatible and in alignment with the DSB's aspirations, and HHS certainly shares the goal of reducing the time from pathogen identification to therapeutic "hit."

NIH has developed numerous collaborations involving various components of DOD. Illustrative examples include the following:

- Development and testing of **therapeutics for smallpox**, with the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) and the Centers for Disease Control and Prevention (CDC)
- Development and testing of a candidate **Ebola vaccine**, with USAMRIID
- Development of **antivirals for Ebola**, with USAMRIID
- Development of a candidate **West Nile virus vaccine**, using a dengue virus "backbone," with Walter Reed Army Institute of Research
- Testing of next-generation **anthrax vaccine**, with the Department of Defense
- Support of the **Orthopoxvirus Genomics and Bioinformatics Resource Center**, with CDC, USAMRIID, and the DoD Defense Advanced Research Projects Agency (DARPA)
- **Genomic sequencing** of Categories A, B, and C pathogens, with DARPA, DoD, USDA, DoE, NSF, CDC, CIA, and others
- Evaluation of **antibiotics**, licensed as therapies for other diseases, to treat anthrax and plague, with USAMRIID and the FDA

Question 8: A key feature of the Administration's proposal involves a grant of permanent, indefinite funding authority to spur development of medical countermeasures by private sector firms.

How do you envision such permanent indefinite funding authority to function?

Who will administer such authority?

Was an analysis done to determine what funding mechanism would best meet the need of developing medical countermeasures to a terrorist threat?

Would such a procedure bypass the annual authorization and appropriations process? If so, why should Operation BioShield be exempted from the usual Congressional oversight function?

To what extent is the Department going to leverage the resources of government funded labs and academia in meeting the goals of Project BioShield?

Response: The goal of BioShield is to ensure that needed countermeasures are developed and procured as quickly as possible, with procurements being driven by threat assessments and scientific/manufacturing feasibility. This legislation is designed to provide industry the assurance that, if it makes the investments necessary to manufacture and bring specifically identified countermeasures to market, the finances will be in place for the Government to procure them quickly. It also enables the Government to respond quickly to unanticipated changes in threats that cannot be addressed with commercially available products. Those that are available commercially—such as ciprofloxacin—or existing vaccines would be purchased through discretionary appropriations. Similarly, if a significant commercial, non-homeland security, market subsequently developed for a BioShield countermeasure, any additional contractual undertakings would have to be funded with discretionary appropriations.

The proposal includes a deliberate governmental process that must be followed for funds to be used. Funds would be available to DHS for obligation only after the President approved a procurement recommendation made jointly by DHS and HHS, in coordination with the Director of OMB. The Congress would be notified of such Presidential approval. Prior to making such a joint recommendation, DHS must, in consultation with other agencies, determine which agents pose a material risk of use against the United States. HHS must assess the public health consequences of such potential use, and determine that a countermeasure is needed but is not commercially available. HHS must also determine there is sufficient scientific basis to conclude the product will ultimately be determined safe and effective, and that production of adequate quantities within five years is feasible. For a procurement contract to be finalized and funds obligated, HHS and the manufacturer must also be confident that the manufacturer can provide those quantities of safe and effective product—no Federal funds could be drawn down against the contracts until a substantial quantity of the product had been delivered. Further discussion of Congressional oversight is in the response to Question 12.

We expect a substantial leveraging of NIH research efforts. Proof of scientific concept must be established before funds would be available for procurement. This proof of concept would often be accomplished through NIH-funded research. BioShield includes added research authorities for NIH to accelerate this type of work.

Question 9: What future efforts (if any) are planned for the Department of Health and Human Services and the Department of Homeland Security to utilize the knowledge within the Russian scientific community to identify existing and potential biological threats, learn how such technical expertise was used in the creation of these agents and cooperate with these persons to aid countermeasure policy making?

The former Russian chief scientist in the bioengineering labs—Dr. Ken Alibek—tells the story of how biological and chemical weapons were created and leaked out of the country. This book titled “Biohazard” and Dr. Alibek may provide crucial insight into how these weapons were made and how America can best guard against them. I would be more than happy to facilitate this effort and provide any assistance you desire.

Response: NIH is an active participant in several important interagency initiatives already underway that address the points you raise.

The U.S. Civilian Research and Development Foundation (CRDF) small grants program is designed to provide catalytic funds to stimulate collaborative research of high scientific merit between U.S. and Former Soviet Union (FSU) scientists. The CRDF is a nonprofit charitable organization created by the United States Government in 1995. This unique public-private partnership promotes scientific and technical collaboration between the United States and the countries of the former Soviet Union (FSU). The CRDF's goals are to:

- Support exceptional peer reviewed research projects that offer scientists and engineers alternatives to emigration and help prevent the dissolution of the scientific and technological infrastructure of the countries of the FSU;
- Advance the transition of weapons scientists to civilian work by funding collaborative non-weapons research and development projects; and
- Help move applied research to the marketplace and bring economic benefits both to the countries of the FSU and to the United States.

In FY 2003, NIAID will fund at least seven CRDF collaborative research projects in various areas of civilian biodefense.

NIH also participates in the DHHS-State Department Biotechnology Engagement Program (BTEP), which provides larger grant support to FSU bioweapons scientists now engaged in civilian research. For example, NIAID currently participates in seven BTEP projects: in HIV/AIDS (3), Tuberculosis (2), Amebiasis (1), and Antimicrobial Drug Resistance (1). These projects are in Russia (5) and Georgia (2).

Since the collapse of the FSU, Russian scientists are the most rapidly growing national group seeking research training in the NIH Visiting Scientists Program. Russian scientists are also eligible to partner with US scientists applying for regular NIH research awards and, under special circumstances, to receive NIH foreign awards. One example is the NIAID Comprehensive International Program for Research on AIDS (CIPRA) award to the University of St. Petersburg. HHS expects that scientifically peer reviewed collaborative research and directly funded research will continue and increase in the future, particularly as NIH-trained biomedical researchers return to Russia and begin competing for research support.

Question 10: Mr. Secretary, there was a project underway jointly with the Armed forces Radiobiology Research Institute (AFMRI) and the Uniformed Services University of the Health Sciences (USUHS) to develop a radioprotectant. There was a hitch due to appropriations, but their product, HE2100 has already shown remarkable re-

sults in animal models. During questions at the hearing, you mentioned negotiations for Prussian Blue. Have you also considered a product such as this, which actually protects against more complications of radiological exposure than potassium iodide or Prussian Blue?

Response: The Department is currently exploring the possibility of adding Prussian Blue, along with additional quantities of other countermeasures for radiation sickness, to the stockpile.

Question 11: What steps have you taken since October 2001 anthrax attacks to have sufficient doses of licensed anthrax vaccine to vaccinate civilian responders?

Do you feel you have a significant CDC stockpile of FDA-licensed vaccine available in the event of a wide-spread attack in the U.S.?

Do you have a short term anthrax preparedness policy that includes expansion of production capacity and a short term stockpile of the current FDA licensed vaccine?

In a letter sent to Bioport on March 6, 2003, you indicated you wanted to focus efforts on developing a new vaccine Why?

Response: An initial amount of \$11,000,000 carried over from the FY 02 budget plus an additional \$22,110,000 in the FY03 budget are allocated to purchase anthrax vaccine. The Strategic National Stockpile (SNS) Program is working with the Department of Defense (DoD) to develop a Memorandum of Understanding (MOU) that will enable the SNS Program to purchase up to 3.0 million doses of this vaccine. Between now and March 2004, approximately 420,000-500,000 doses will be available for purchase. The remainder of the 3.0 million doses may be requested for purchase after March 2004.

The current on-hand availability of FDA-licensed vaccine is 381 vials with 10 doses per vial. This is enough capability to vaccinate 1270 people (3 doses/person). The SNS also contains 20,878 vials of IND product, enough to vaccinate 69,593 people.

The SNS Program is currently finalizing an MOU with DoD for purchase of the licensed product only. DoD holds the contract for production with the company. The SNS Program cannot request increased production capacity; this would have to be done through DoD.

With respect to the question concerning the letter to Bioport, what is needed is a new vaccine that, by comparison with the current licensed vaccine manufactured by Bioport, (1) is less reactogenic, (2) is easier to manufacture, (3) is more uniform, (4) has higher immunogenicity, (5) requires fewer doses before an acceptable immunity is established, and (6) has a reliable supply.

Question 12: This proposal provides permanent and indefinite funding authority under the guise that it is necessary to spur the development of medical countermeasures in the private sector. Will this authority bypass the annual authorization and appropriations process? If so, why shouldn't BioShield be subject to regular Congressional oversight?

Congress wants to develop needed vaccines and drugs to fight bioterrorism. If the Administration requests funds for this, I am confident that Congress will meet these requests. Wouldn't it be a feasible option to use the regular order for crafting the spending authority under this measure? Or, is the Administration merely requesting this funding outside of the normal appropriations process because it did not want to reduce funding for domestic programs already shortchanged in the fiscal 2004 request?

Response: We have carefully developed this legislation to ensure fiscal responsibility while providing the flexibility needed to respond to changing threat scenarios and the financial assurances industry needs to develop/manufacture essential countermeasures that do not have a commercial market. The requirements for the use of these funds are stringent, and limited to products for which there is not a significant commercial market. The Administration anticipates on-going Congressional oversight. Each procurement must be approved by the President, with the Congress notified of each such approval. HHS would expect activities—and results—under BioShield to be a regular topic of discussion in hearings in a wide range of hearings for both DHS and HHS, including authorizing, oversight, and appropriations committees.

Question 13: As you know, the normal peer review procedure in the case of grants, contracts, and cooperative agreements for biomedical countermeasure research and development (R&D) is an initial study section review and an advisory council review. The two-stage peer review process is the most well-regarded in the world. Yet, this bill would waive these procedures.

Can you please tell the Committee what safeguards will be put in place to ensure the new, expedited process is as sound and safe as the current process provides for?

Can you also address concerns that because this process will be done behind closed doors and that competitive procedures can be waived that the process will not either be fair or produce the best results? What safeguards will be put in place to ensure the companies with the best proposals, not those in good standing with the Administration, will be awarded contracts?

Response: The NIH system of peer review is, indeed, admired and emulated around the world. The expedited peer review provision in the BioShield bill is aimed at shortening the peer review process (which often can take 9 months or more), but not diminishing its quality. Expedited peer review, carried out in consultation with appropriate scientific experts, would determine scientific and technical merit of proposals and assess the likely contribution to the field of research. Furthermore, under the proposed provision, the authority to expedite peer review may be exercised only in the case of pressing research and development of countermeasures urgently needed to combat a biological agent that may cause a public health emergency and affect national security.

As provided elsewhere in the Administration's bill, some contracts may be awarded through a noncompetitive process when it is known that only a limited number of companies are available to submit proposals. (See response to Question 24). However, peer review procedures (either regular or expedited) would be employed to review proposals submitted through the noncompetitive process, as well as all contract proposals that are submitted through any normal competitive processes.

Question 14: The proposal allows for the use of unapproved drugs or devices in an actual or potential national public health emergency. What compensation protections will be provided the general public if the government distributes a drug that causes severe or disabling side effects?

Response: Section 4 of the bill authorizes use of medical products in emergencies if the Secretary concludes that it is reasonable to believe, based on the totality of available scientific evidence, including available data from adequate and well-controlled clinical trials, that the product may be effective against a serious or life-threatening disease or condition; that the benefits of the product outweigh the risks; and that there is no adequate, approved, and available alternative to the product for such purpose. Thus, the risk that a distributed drug will cause severe or disabling effects should be reduced as much as possible prior to any distribution.

If, nevertheless, there is an injury, there are several potential sources for compensation, depending on the circumstances. Compensation may be available from an individual's insurer. If the individual received the product in connection with his/her employment, compensation may be available under a workmen's compensation program (including, for Federal employees, the Federal Employee Compensation Act). If the injury results from negligence or wrongdoing in the manufacture or administration of the product, compensation may be available through the tort law system (including, for negligence or wrongdoing by Government employees, the Federal Tort Claims Act, where the requirements of that statute are met). If the countermeasure is part of the Strategic National Stockpile, the manufacturer may have been indemnified by HHS pursuant to Public Law 85-804. If the countermeasure is related to smallpox, special provisions may apply—Section 304 of the Homeland Security Act creates a Federal Tort Claims Act remedy in certain circumstances, and Public Law 108-20, the Smallpox Emergency Personnel Act of 2003, provides compensation to individuals receiving smallpox vaccine under HHS recommendations.

Question 15: Can you more clearly define under what circumstances you have the authority to declare an emergency and distribute unapproved, unlicensed drugs?

Response: In order for the Secretary of HHS to issue an emergency use authorization for a product, there must be a determination—

- (A) by the Secretary of Homeland Security, that there is a domestic emergency (or a significant potential of a domestic emergency) involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent;
- (B) by the Secretary of Defense, that there is a military emergency (or a significant potential of a military emergency) involving a heightened risk to United States military forces of attack with a biological, chemical, radiological, or nuclear agent; or
- (C) by the Secretary of a public health emergency under section 319 of the Public Health Service Act, affecting national security and involving a specified biological, chemical, radiological, or nuclear agent or a specified disease or condition that may be attributable to such agent.

With respect to distribution of unapproved, unlicensed drugs, pursuant to the Bio- Shield legislation, such products could be introduced into interstate commerce if the Secretary issues an authorization for emergency use of the product. Prior to issuing such an authorization, certain criteria have to be met under the proposed legislation including a conclusion by the Secretary—

- (1) that an agent specified in a declaration under subsection (b) can cause a serious or life threatening disease or condition;
- (2) that, based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that—
 - (A) the product may be effective in detecting, diagnosing, treating, or preventing—
 - (i) such disease or condition; or
 - (ii) a serious or life-threatening disease or condition caused by a product authorized under this section or approved under this Act or the Public Health Service Act, for detecting, diagnosing, treating, or preventing such a disease or condition caused by such an agent; and
 - (B) the known and potential benefits of the product, when used to detect, diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product;
- (3) that there is no adequate, approved, and available alternative to the product for detecting, diagnosing, preventing, or treating such disease or condition; and
- (4) that such other criteria as the Secretary may by regulation prescribe are satisfied.

Question 16: The measure states that the Administration has the authority to procure medical countermeasures for the inclusion in the DHS strategic national stockpile. Is there any instance where the Administration will be procuring a countermeasure for outside the stockpile or “emergency use”?

Response: The Government may purchase limited quantities of a countermeasure for research, either under the research and development section of the Project BioShield bill or for other research. It may procure countermeasures for use in Government health care facilities (IHS hospitals, DoD and VA hospitals). (These situations would entail using regular annual appropriations rather than the special fund created by the countermeasure procurement section of the bill.) The Government may also procure countermeasures for the Strategic National Stockpile other than through the mechanism supplied by the Project BioShield bill—for example, if there is a commercial market for a particular countermeasure, the Government may procure it for the Stockpile using ordinary annual appropriations. Countermeasures purchased for the Strategic National Stockpile, either under Project BioShield or the annual stockpile discretionary appropriation, can be transferred to DoD or other federal agencies on a reimbursable basis.

Question 17: Can drugs already on the market for other uses be entered into BioShield if it's shown that the drug can be developed into a countermeasure?

Response: It is unclear what is intended by the phrase “entered into BioShield” in this question. If that phrase is intended to refer to whether a product can receive an emergency use authorization in response to a declared emergency relating to chemical, biological, radiological or nuclear attack, the proposed legislation would authorize the Secretary to provide an emergency authorization for such a product, even if it is currently licensed for another use.

Question 18: Mr. Secretary, in his written testimony, Dr. Baker underscores the importance of including academic research institutions, as well as private innovator companies, in our efforts to develop countermeasures to bioterrorism.

In my opening statement, I referenced the work being done at Baylor College of Medicine and other universities. Can you tell us how Project BioShield would further the work being done at our nation's universities?

Response: The Department is in complete agreement about the importance of including academic research institutions in its efforts to develop countermeasures for bioterrorism. To that end, NIAID has markedly intensified, expanded, and accelerated its ongoing basic and applied research programs relating to biodefense, and has developed a total of 52 biodefense initiatives to stimulate basic research and development of countermeasures in 2002 and 2003. Most of these initiatives are specifically addressed to, or entail collaborations involving academic research centers. (Additional detailed information is contained in the response to question 22 below.)

BioShield will build on these investments and help ensure that HHS scientists, working with industry, can actually develop the tools of diagnosis, treatment and prevention that will allow HHS to respond effectively to and deter future bioterrorist attacks on American citizens. Project BioShield will provide an additional and extremely important stimulus to the basic research engine of academia by greatly facilitating translation of advances in fundamental research into countermeasures to defend civilians. It will also create many opportunities for industry-funded applied research in academic research centers as industry carries out the studies required for advanced development, production, and licensure of new interventions so that they can be added to the Strategic National Stockpile.

Question 19: The emergency use component of this bill would allow the Secretary to make certain unapproved products available to the public in an expedited fashion in the event of a bioterrorist attack. Because these products would likely not be fully tested at this point, there is a possibility that harmful side effects might be discovered after widespread use by the public.

We already are trying to address such a situation with legislation to compensate persons who are harmed as the result of a smallpox vaccination. Many Members of this Committee have been locked in these difficult negotiations.

Has the Administration given any thought to how it would compensate individuals who could be harmed as a result of taking an untested product? Some of our witnesses on the next panel will testify that this liability issue could discourage larger manufacturers from really engaging in new product development. Does this legislation address the liability concerns?

Response: As noted in the response to Question 14, the emergency use authorization section includes several provisions that should reduce the risk of harm, and, in the event of harm, there are several possible sources for compensation, including insurance, workmen's compensation programs, the tort law system, and certain special statutory provisions concerning smallpox countermeasures and the Strategic National Stockpile.

There are existing legal provisions that address manufacturers' concerns about potential liability resulting from product liability tort actions. (1) If the product in question is designated by the Secretary of Homeland Security as a "qualified anti-terrorism technology," as defined in the SAFETY Act (sections 861-865 of the Homeland Security Act of 2002), the seller of the product receives certain protections from liability in cases based on acts of terrorism. The statute gives federal courts exclusive jurisdiction over such claims, and it limits damages in such cases (precluding punitive damages, limiting non-economic damages, and limiting total damages to the amount of liability insurance coverage that the seller can obtain without unreasonably distorting the sales price of the technology). The statute also allows the seller to assert the "government contractor" defense (which applies the Government's sovereign immunity to Government contractors), absent a showing that the seller committed fraud or willful misconduct in giving the Government the information used to approve the product as a "qualified anti-terrorism technology."

(2) The government contractor defense also protects a manufacturer of a product that is not designated as a "qualified anti-terrorism technology," if the product is produced pursuant to a Government contract; the Government has prepared or approved reasonably precise specifications; the product conforms to such specifications; and the manufacturer warned the Government of any dangers known to the contractor, but not known to the Government.

(3) Finally, the Department may, under certain circumstances, indemnify countermeasure manufacturers or sellers under P.L. 85-804.

Question 20: Mr. Secretary, many on this panel have already expressed their concern, and general surprise at the Administration's decision to provide unspecified, permanent funding for this program. This provision certainly flies in the face of the Administration's previous positions on many issues. Many of us are uncomfortable with writing a blank check of this nature, especially since the Congress controls the purse strings. How do you justify this change of policy?

Response: Pharmaceutical manufacturers have expressed concerns about investing substantial resources to develop a countermeasure, only to find out down the line that the Government cannot make available sufficient funds to purchase the product. Permanent funding will help to provide assurance to the industry that, in the event an effective countermeasure is available, there will be a market for such a countermeasure and the Government will have sufficient funding available for purchase.

Question 21: Similarly, based on my read of this legislation, it looks like the Secretary would have the blanket authority to expedite scientific peer review requirements under "urgent circumstances." Would the Secretary act unilaterally to determine what products could bypass FDA approval? Does the legislation require consultation with the NIH, the Congress or consumer groups? I appreciate the need to cut the red tape in some of these situations but I have concerns that this provision could be broadened to include products that might not be directly related to bioterrorism.

Response: The legislation would authorize the Secretary to issue an emergency use authorization if specific criteria are met for the duration of the declared emergency. It is not HHS's intention to permit emergency use authorizations except for products that could be used in response to a domestic emergency involving biological, chemical, radiological or nuclear agents, a military emergency involving those agents, or a public health emergency. The legislation does not preclude the Sec-

retary from consulting with relevant government and non-governmental public health experts.

Question 22: Mr. Secretary, can you paint a picture of some of the work that is currently being done within NIH to help develop countermeasures? We have heard a lot about how the proposal would incentivize research at private companies, but is there a desire to expand the work being done at our public institutes?

Response: The National Institute of Allergy and Infectious Diseases (NIAID) is the principal institute within the National Institutes of Health that supports biodefense research. The explicit goal of NIAID's biodefense research is to develop the tools and countermeasures that are necessary to protect civilians from potential agents of bioterrorism. The NIAID's biodefense strategic plan includes significant investments in internal and extramural basic research, including studies of microbial biology and host responses to those microbes. This basic research provides the substrate of new knowledge from which new vaccines, therapies, and diagnostic tools will emerge. One goal of Project BioShield is to encourage industry to invest in the process of translating these basic scientific discoveries into deliverable products. NIAID is also making substantial investments in national research resources such as laboratory facilities, centers of excellence, and a national reagent repository. To implement these plans, NIAID has launched a total of 52 biodefense initiatives in 2002 and 2003. The majority of these are either directed toward academic research centers or will entail collaborations that involve academic centers. Examples include the following:

Biodefense and Emerging Infectious Disease Research Opportunities: Intended to encourage the submission of investigator-initiated research grant applications in biodefense and select emerging infectious diseases. The goal is to expedite research leading to the diagnosis, prevention and treatment of diseases caused by potential bioterrorism agents.

Rapid Response Grant Program on Bioterrorism-related Research: Funded more than sixty projects in FY02 to support innovative research targeted at the design and development of specific diagnostics, therapies, and prevention strategies for Category A biological diseases.

Partnerships for Novel Therapeutic, Diagnostic, and Vector Control Strategies in Infectious Diseases: Awarded six Partnership Grants in FY02 to support collaborative partnerships between government, academia, and the private sector to develop novel biodefense products.

Biodefense Partnerships: Vaccines, Adjuvants, Therapeutics, Diagnostics, and Resources: Facilitates collaborative partnerships between government, academia, and the private sector to develop novel biodefense products.

Cooperative Research for the Development of Vaccines, Adjuvants, Therapeutics, Immunotherapeutics, and Diagnostics for Biodefense Program: Facilitates the design and development of vaccines, therapeutics, adjuvants, and diagnostics for NIAID Category A-C priority pathogens and their toxins to help translate basic research knowledge into new biodefense products.

Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research: Establishes 7 to 8 academic research centers of excellence that will not only provide state-of-the-science research capacity, but will also link to the Centers for Disease Control and Prevention and to state and local health departments to provide permanent, regional expertise on agents of bioterror and other emerging and re-emerging diseases.

Construction and Renovation of Biosafety Laboratory Facilities: Funding, mainly to academic research centers, to design, build, renovate, and certify bio-containment laboratories, addressing a critical national shortage of facilities in which to safely carry out some essential biodefense research and development.

Division of Intramural Research: Intramural program has expanded research efforts for many Categories A, B, and C agents and initiated plans to construct Biosafety level 3 and 4 facilities to enable safe research on medical countermeasures against bioterrorism.

Question 23: What procedures will HHS employ to study the effectiveness of a countermeasure after it's been employed in an emergency, and will it have to then go through a more elaborate FDA approval process in a non-crisis situation?

Response: The legislation provides the Secretary with authority to establish conditions for use relating to an emergency authorization, including limitations on distribution, on who may administer the product, and on the performance of studies and clinical trials. In addition, the legislation authorizes the Secretary to impose requirements for adverse event reporting, to impose additional recordkeeping and records access requirements and to impose good manufacturing practices. In a non-crisis situation, a countermeasure would have to go through FDA's statutorily required pre-market approval process.

Question 24: Would you expound on the use of the noncompetitive process mechanism you propose in the bill?

Response: Current Federal procurement regulations permit noncompetitive contracting when it is known with certainty that only one source is available. The provision for a noncompetitive process proposed in the Administration's BioShield bill would permit HHS to award contracts without competition when the number of available sources is greater than one, but highly limited. This authority would be used to bypass a number of time-consuming steps, but the Department would continue to undertake necessary steps, including effective acquisition planning, to ensure contracts are awarded at fair and reasonable prices and include terms and conditions that are in the best interest of the government. In biomedical research and development, especially for vaccines and other complex biological materials, it is frequently the case that only a few companies possess a viable candidate product or technology. Without these authorities, HHS would be obligated to follow the complete process of solicitation and competitive contracting, even when it knows that only a very limited number of companies could submit proposals.

Question 25: With single source procurement contracts for countermeasures, are the profit margin and rate of return pre-established in the contract?

Response: Under the Federal Acquisition Regulation, single source procurement contracts do not contain a profit margin or rate of return. If the contract is a firm-fixed price contract, the Government is always charged the negotiated unit price in the contract. If the contract is a cost reimbursement, the contract is priced on the basis of negotiated allowable costs plus a fixed fee, or such costs plus cost containment or performance incentives.

Question 26: As is customary in conventional government procurement, couldn't HHS simply expedite the RAP and awarding process for developing countermeasures? Wouldn't a competitive bidding process serve the public interest and public goals better?

Response: The Department's intent is not to forego competition, but rather to use highly streamlined forms of competition (including application of simplified acquisition techniques) whenever possible and to use noncompetitive processes, only if necessary and justified. While current laws and regulations provide agencies with considerable flexibility, including the ability to conduct efficient source selections when there are many potential contractors, the current framework does not fully address the environment which the Department routinely anticipates for the types of needs, addressed by its BioShield legislation—namely, very limited numbers of companies (but perhaps more than one) that possess a viable candidate product or technology to meet pressing demands for effective countermeasures. HHS fully appreciates the benefits that competition provides and intends to engage in good planning and market research in all acquisitions so that it can take advantage of competition whenever possible and ensure well structured contracts with appropriate incentives for successful results in all contracts in furtherance of Project BioShield.

Question 27: Better still, why shouldn't DHS start contracting immediately to develop countermeasures for a National Institute of Allergy and Infectious Disease High Threat List ("A List") Toxins?

Response: HHS, through the NIAID/NIH, has the mandate from both the Congress and the Administration to develop countermeasures for biodefense because HHS, NIH, and NIAID have extensive resources of scientific talent and expertise, and a long and proven track record of success in developing drugs and vaccines for infectious diseases. DHS cannot, in any reasonable timeframe, replicate this experience and expertise. Providing HHS with the special (and targeted) authorities of Project BioShield for the scientific experts at the NIH who are already in place and know how to use them would enable NIH to immediately accelerate research and development of countermeasures for agents that may cause a public health emergency affecting national security. HHS will continue to work collaboratively with DHS to coordinate research and development priorities and activities between the departments.

Question 28: Much of the debate on preparedness revolves around biological toxins. Is there anything specifically that's being done to develop countermeasures for chemical agents?

Response: The NIH is actively assessing its opportunities to assist the national effort in this regard. Several steps have already been taken. For example, NIAID initiated a meeting with the leadership of the National Academy of Sciences to explore potential areas of collaboration and cooperation, following the NAS Report "Making the Nation Safer: The Role of Science and Technology in Countering Terrorism." NIAID also convened an expert panel to help frame the "landscape" of biomedical research and development needs in this area. Within this framework, several NIH Institutes and Centers are exploring opportunities to address needs in this

area. Across the NIH, these efforts will be coordinated through the NIH Biodefense Research Coordinating Committee with the NAS and other relevant organizations and federal agencies.

Question 29: Two major issues in countermeasure technology development are economic incentives and liability concerns. In your testimony, you mentioned that grants and contracts might not be sufficient for developing the public/private partnership. How will Project BioShield address these issues in order to expedite the development of the next generation of countermeasures?

Response: Section 3 of the bill, the biomedical countermeasures procurement section, facilitates the creation of markets for certain biodefense products that, absent new incentives, would likely be inadequate to attract sufficient investment by the private sector to meet emerging needs for development of countermeasures. This proposal complements existing statutes that support technology transfer and public/private partnerships, including the Bayh-Dole Act and the Federal Technology Transfer Act. Moreover, the bill would enable the Department to award grants, contracts, and cooperative agreements for research and development of medical countermeasures through expedited and more flexible procedures to enhance the Department's ability to accelerate research on and development of innovations applicable to biodefense.

In general, grantees and contractors are expected to carry insurance to cover research and development activities. There is some concern that insurance coverage will not be sufficient, or available for countermeasure research and development, but existing mechanisms, as discussed in the Department's responses to questions 14 and 19, would address such concerns.

Question 30: Mr. Secretary, it is my understanding that the U.S. Armed Forces Radiobiology Research Institute (AFRRI) is currently in partnership with a private drug company to conduct Phase III trials of a compound, HE-2100, that has shown early promise in counteracting the immuno-depleting effects of nuclear radiation. Considering the promising nature of this and possibly other radioprotectant drug candidates, can you elaborate on how Project BioShield or other initiatives would specifically enhance the ability to aid in the development and procurement of these drugs?

Response: The U.S. Armed Forces Radiobiology Research Institute has published several articles on the drug HE-2100. The compound appears to be well-tolerated in high doses in mice and is reported to have modest radioprotectant activity when administered prior to radiation exposure. HE-2100 is the subject of a Cooperative Research and Development Agreement between the Armed Forces Radiobiology Research Institute, the Uniformed Services University of the Health Sciences, and Hollis-Eden Pharmaceuticals Inc. At this point in its development, further preclinical and animal model work is necessary to determine if the compound provides radioprotectant activity when it is administered FOLLOWING radiation exposure. The absence of such post-exposure radioprotectant activity would significantly limit the role for HE-2100 in civilian biodefense. In addition, research is also needed to establish that the compound is safe and efficacious for civilian biodefense use. Thus, it is not a candidate for Project BioShield at this time.

Question 31: Mr. Secretary, it is also my understanding that the current fiscal year budget for AFRRI is in some degree of doubt, and that the agency currently does not and may not in the future have the resources to aggressively develop promising radioprotectant drug candidates like HE-2100. Do you see a role for HHS in directly aiding in the development of this compound, considering it is AFRRI's leading radioprotectant candidate?

Response: HHS, through NIH, has recently initiated discussions with AFRRI and a number of other organizations, including the National Academy of Sciences, to explore how it might contribute to research and development on countermeasures for nuclear/radiological and chemical terrorism. While HE-2100 appears to have some promise as a radioprotectant from a DoD perspective, its interest to and priority for civilian indications remain to be determined, but are dependent on the development of evidence of radioprotectant activity when administered AFTER radiation exposure. This would be a minimal requirement for a radioprotectant destined for civilian biodefense use.

It is also important to note that there are other possible opportunities to research and develop potential radioprotectant countermeasures for civilian biodefense, too. As with HE-2100, HHS is also in the process of assessing their merit, interest, and possible priority for support.

Question 32: How much do you estimate Project BioShield will cost? What costs are likely to be incurred for fiscal years 2003 and 2004? Over the next ten year period? What is the basis for the Administration's cost estimates?

Response: We estimate costs of \$5.6 billion over 10 years, including \$890 million in FY 2004. No FY 2003 spending is assumed. These estimates are based on a combination of assessments of threats, a determination of which threats cannot be addressed by commercially available products, and current scientific judgements of what countermeasures can be produced during this time frame. FY 2004 estimates reflect research NIH believes is nearing proof of scientific concept, with funds expected to be used for a new anthrax vaccine, a smallpox vaccine that is safe for those with medical conditions that contraindicate use of current vaccines, and protection against botulism.

Question 33: To what extent has the Administration worked closely with the industry in developing its program to develop these countermeasures?

Response: See the answer to question #5

Question 34: In what ways does BioShield focus on procuring countermeasures that become available?

Response: The countermeasure procurement section of the Project BioShield bill requires the Secretaries of Homeland Security and of HHS to make ongoing assessments of which chemical, biological, radiological, and nuclear agents pose material risks of use against the United States population and of the effect on public health of possible use of such agents. It also requires ongoing determinations of agents for which countermeasures are necessary to protect public health, and ongoing assessments by the two Secretaries of the availability and appropriateness of specific countermeasures to address particular threats. It requires the Secretary of HHS to identify countermeasures that are appropriate for procurement with the special fund.

Question 35: In what ways does it serve as an incentive for long-term research projects?

Response: Project BioShield provides a critically important incentive for long-term research and development of drugs and vaccines (countermeasures) for bioterrorism preparedness. Many such countermeasures have essentially no market other than the U.S. government. In the absence of a market, there is no incentive for private sector interest or involvement in development of these countermeasures because fiduciary responsibilities to shareholders channel priorities toward other, more lucrative opportunities. This is particularly the case with vaccines, where production is complex and costs can be extremely high. BioShield creates the missing "market" for these countermeasures in two ways. The Government may contract to purchase a specified quantity of the product if there are data supporting a reasonable conclusion that the product can be approved or licensed within five years. For products that are further away from approval or licensure, the availability of the permanent indefinite appropriation will assure companies that, if their research and development do yield an appropriate product, the Government will be able to purchase it even if there is no commercial market. Under these circumstances, it is more likely that companies will be willing to assume the risks inherent in research and development.

Question 36: Will BioShield define a market for a countermeasure in advance so that a company can evaluate it BEFORE it begins a major long-term research project to develop it? How specific will this definition be? Does the government, in effect, guarantee that this is the market that will exist if the company successfully develops the countermeasures?

Response: Project BioShield is designed to achieve results, and the countermeasure procurement section of the bill envisions the Government entering into firm purchase obligations. If the product does not yet have approval or licensure, the Government may enter into a procurement contract under the bill as long as there is clinical experience or research data supporting a reasonable conclusion that the product can be approved or licensed within five years. For products that are further away from approval or licensure, the procurement section will still enhance the incentives for a company to enter into the research project—the availability of the permanent indefinite appropriation will assure companies that, if their research yields an appropriate product, the Government will have the ability to purchase it even if there is no commercial market.

Finally, it should be kept in mind that the research and development section of the bill provides flexible mechanisms for procurement of research on countermeasures.

Question 37: If a company believes it has successfully developed a countermeasure and it is not, in fact, awarded the procurement, what recourse does it have?

Response: The first recourse for a disappointed bidder would be to protest to the agency and cite section 33.103 of the Federal Acquisition Regulation. Beyond this there are two other avenues for disappointed bidders to challenge Government contract award decisions. First, under the Tucker Act (28 U.S.C. 1491(a)(1)), contractors

may file bid protests challenging award decisions in the U.S. Court of Federal Claims. Second, pursuant to provisions within the Competition in Contracting Act (31 U.S.C. §§3551-3556), contractors may also file bid protests at the General Accounting Office (GAO).

Question 38: The legislation only applies to procurement where “production and delivery within five years of sufficient quantities of the product...is reasonably expected to be feasible”. Why did you limit the focus to this time period? What types of research is likely to be covered by this time frame and what types is likely to be excluded? What types of research is likely to be covered by this time frame and what types is likely to be excluded?

Response: Drug and vaccine development is fraught with unpredictability. A very high percentage of candidate drugs and vaccines fail development. The five year window was chosen because it is virtually impossible to make reasonable predictions of the feasibility of “production and delivery...of sufficient quantities of the product” in longer time horizons.